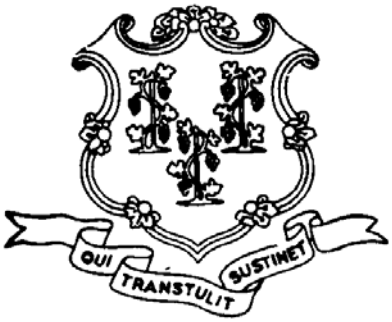
Connecticut Comprehensive Drug Laws



August 2005

Prepared by the

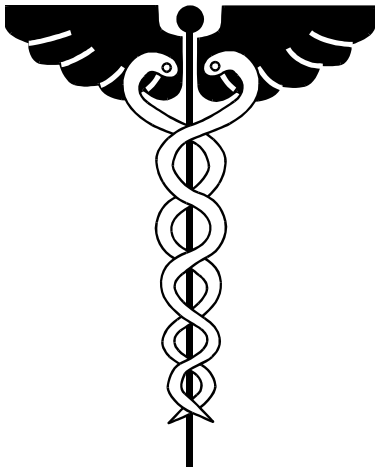
DEPARTMENT OF CONSUMER PROTECTION

Drug Control Division Commission of Pharmacy

Connecticut Comprehensive Drug Laws
Updated through August 2005

S E C T I O N I

Connecticut General Statutes



CHAPTER 400j

PHARMACY

Part I
Commission of Pharmacy, Powers and Duties

Sec. 20-570. Title. Sections 20-570 to 20-630, inclusive, may be cited as the "Pharmacy Practice Act".

Sec. 20-571. Definitions. As used in sections 20-570 to 20-630 inclusive, unless the context otherwise requires:

(1) **"Administer"** means the direct application of a drug or device to the body of a patient or research subject by injection, inhalation, ingestion or any other means;

(2) **"Care Giving Institution"** means an institution that provides medical services and is licensed, operated, certified or approved by the Commissioner of Public Health and Addiction Services, the Commissioner of Mental Retardation or the Commissioner of Mental Health;

(3) **"Commission"** means the Commission of Pharmacy appointed under the provisions of section 20-572;

(4) **"Commissioner"** means the Commissioner of Consumer Protection;

(5) **"Compound"** means to combine, mix or put together two or more ingredients pursuant to a prescription and includes the preparation of drugs or devices in anticipation of prescriptions based on routine, regularly-observed prescribing patterns;

(6) **"Correctional or juvenile training institution"** means a facility for the detention or incarceration of persons convicted or accused of crimes or offenses or for training of delinquent juveniles, including those state facilities under the jurisdiction of the Commissioner of Correction, training schools for delinquent juveniles and any other facilities operated by the state or municipalities for such detention, incarceration or training;

(7) **"Device"** means instruments, apparatus and contrivances, including their components, parts and accessories, intended (A) for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or other animals, or (B) to affect the structure or any function of the body of humans or other animals, but does not include contact lenses;

(8) **"Department"** means the Department of Consumer Protection;

(9) **"Dispense"** means those acts of processing a drug or device for delivery or for administration for a patient pursuant to a prescription consisting of: (A) comparing the directions on the label with the directions on the prescription to determine accuracy; (B) the selection of the drug or device from stock to fill the prescription; (C) the counting, measuring, compounding or preparation of the drug or device; (D) the placing of the drug or device in the proper container; (E) the affixing of the label to the container and; (F) the addition to a written prescription of any required notations. "Dispense" does not include the acts of delivering a drug or device to a patient or of administering the drug or device to the patient;

(10) **"Dispensing outpatient facility"** means a facility operated by a corporation or municipality which provides medical services to patients on an outpatient basis and which maintains stocks of drugs for dispensing of drugs on a regular basis to patients for use of he premises;

(11) **"Drug"** means (A) an article recognized in the United States Pharmacopoeia, Official Homeopathic Pharmacopoeia of the United States or Official National Formulary, or any supplement to any of them, (B) an article intended for use in the diagnosis, cure, mitigation, treatment or prevention of decease in humans or other animals, (C) an article other than food, intended to affect the structure or any function of the body of humans or any other animal, and (D)

an article intended for use as a component of any article specified in this subdivision, but does not include a device;

(12) **"Institutional Pharmacy"** means that area within a care-giving institution or within a correctional or juvenile training institution, commonly known as the pharmacy, that is under the direct charge of a pharmacist and in which drugs are stored and dispensed;

(13) **"Legend Device"** means a device that is required by applicable federal or state law to be dispensed pursuant only to a prescription or is restricted to use by prescribing practitioners only or that, under federal law, is required to bear either of the following legends: (A) "RX ONLY" in accordance with guidelines established in the federal Food, Drug and Cosmetic Act; or (B) "CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE FOR USE BY OR ON THE ORDER OF A LICENSED VETERINARIAN.";

(14) **"Legend Drug"** means a drug that is required by any applicable federal or state law to be dispensed pursuant only to a prescription or is restricted to use by prescribing practitioners only, or means a drug that, under federal law, is required to bear either of the following legends: (A) "RX ONLY" in accordance with guidelines established in the federal Food, Drug and Cosmetic Act; or (B) "CAUTION: FEDERAL LAW RESTRICTS THIS DRUG FOR USE BY OR ON THE ORDER OF A LICENSED VETERINARIAN.";

(15) **"Nonlegend drug"** means a drug that is not a legend drug;

(16) **"Person"** means an individual, corporation, business trust, estate trust, partnership, association, joint venture or any other legal or commercial entity;

(17) **"Pharmacist"** means an individual licensed to practice pharmacy under the provisions of section 20-590, 20-591, 20-592 or 20-593, and who is thereby recognized as a health care provider by the state of connecticut;

(18) **"Pharmacy"** means a place of business where drugs may be sold at retail and for which a pharmacy license has been issued to an applicant under the provisions of section 20-594;

(19) **"Pharmacy intern"** means an individual registered under the provisions of section 20-598;

(20) **"Pharmacy technician"** means an individual who is registered with the department and qualified in accordance with section 1 of Public Act 98-31;

((21) **"Practice of pharmacy"** or **"to practice pharmacy"** means the sum total of knowledge, understanding, judgments, procedures, securities, controls and ethics used by a pharmacist to assure optimal safety and accuracy in the distributing, dispensing and use of drugs and devices;

(22) **"Prescribing practitioner"** means an individual licensed by the State of Connecticut, any other state of the United States, the District of Columbia, the Commonwealth of Puerto Rico or any territory or insular possession subject to the jurisdiction of the United States who is authorized to issue a prescription within the scope of the individual's practice;

(23) **"Prescription"** means a lawful order of a prescribing practitioner transmitted either orally, in writing or by electronic means for a drug or device for a specific patient;

(24) **"Sale"** includes barter, exchange or gift or offer and each such transaction made by a person whether as principal proprietor, agent, servant or employee; and

(25) **"Substitute"** means to dispense without the prescribing practitioner's express authorization a different drug product than the drug product prescribed.

Sec. 20-572. Commission of Pharmacy. Appointment and term of members. There shall be in the department a Commission of Pharmacy which shall consist of six persons appointed by the governor, subject to the provisions of section 4-9a, four of whom shall be pharmacists each actively engaged in the practice of pharmacy on a full-time basis during the term of such person's appointment in this state and two of whom shall be public members. At least two of the pharmacist members shall be community retail pharmacists and at least one of the pharmacist members shall be

a pharmacist employed on a full-time basis as a pharmacist in a hospital in the state during the term of such pharmacist member's appointment. Members of the commission may be selected from lists of individuals nominated by then Connecticut Pharmacists Association or by other professional associations of pharmacists or pharmacies. Any vacancy on the commission shall be filled by the governor.

Sec. 20-573. Meetings of Commission. Records. (a) Meetings of the commission for the purpose of conducting business of the commission shall be held at the office of the commission at least six times per calendar year and at such other times and places in each year as the chairperson or a majority of the commission deems necessary.

(b) The commission shall keep a copy of its proceedings. A copy of any such record, certified by the commissioner shall be admitted as evidence in any civil or criminal action in lieu of the record.

Sec. 20-574. General supervision. The commissioner shall exercise general supervision over the operations of the commission pursuant to sections 20-570 to 20-630, inclusive

Sec. 20-575. Powers and responsibilities. (a) The Commission shall administer and enforce the provisions of sections 20-570 to 20-630, inclusive. The commission has all powers specifically granted in the general statutes, including the powers set forth in sections 21a-7 and 21a-9 of the general statutes, and all further powers that are reasonable and necessary to enable the commission to protect the public interest in accordance with the duties imposed by sections 20-570 to 20-630, inclusive.

(b) The commission may compel attendance of witnesses and the production of documents by subpoena and may administer oaths. If any person fails to appear , testify or produce any document when so ordered , a judge of the superior court may, upon application of the commission, make such order as may be appropriate to enforce this subsection.

(c) The commission may apply to the superior court for and the court may, upon hearing and for cause shown, grant a temporary or permanent injunction enjoining any person from violating any provision of sections 20-570 to 20-630, inclusive, or any regulation adopted in accordance with chapter 54 by the commissioner, with the advice and assistance of the commission, pursuant to sections 20-570 to 20-630, inclusive, irrespective of whether an adequate remedy at law exists. The commissioner may also apply to the superior court for, and the court shall have jurisdiction to grant, a temporary restraining order pending a hearing.

(d) An application to the superior court under subsection (b) or (c) of this section shall be brought by the attorney general.

Sec. 20-576. Regulations. (a) The commissioner may, with the advice and assistance of the commission, adopt regulations, in accordance with chapter 54, to govern the performance of the commission's duties, the practice of pharmacy and the business of retailing drugs and devices. Such regulations may include, but are not limited to, provisions (1) concerning the licensing of any pharmacist or pharmacy, disciplinary action that may be taken against a licensee, the conduct of a pharmacist and the operation of a pharmacy, (2) specifying various classes of pharmacy licenses issued under section 20-594, including, but not limited to, licenses for infusion therapy pharmacies and nuclear pharmacies and specifying requirements for operation of pharmacies under the classes of pharmacy licenses permitted under the regulations, (3) concerning creation and maintenance of prescription records, and (4) concerning registration and activities of pharmacy interns, registered pharmacy technicians and certified pharmacy technicians.

(b) The commissioner shall, with the advice and assistance of the commission, adopt regulations, in accordance with chapter 54, governing (1) the storage and retrieval of prescription information for noncontrolled substances, including refills, by pharmacists through the use of electronic data processing systems or other systems for the efficient storage and retrieval of information, (2) the operation of institutional pharmacies pursuant to chapters 368a and 418, sections 17a-210 to 17a-273, inclusive, as amended, and 19a-490 to 19a-520, inclusive, as amended, and sections 20-570 to 20-630, inclusive, and (3) the activities of pharmacy technicians in pharmacies and institutional pharmacies, including ratios of registered pharmacy technicians and certified pharmacy technicians to pharmacists in pharmacies and institutional pharmacies.

Sec. 20-577. Employment of inspectors by Commissioner of Consumer Protection; duties. Inspection of juvenile training and care-giving institutions,dispensing outpatient facilities and institutional pharmacies by commissioner. (a) The commissioner shall employ inspectors whose duty it shall be to inspect all pharmacies and other places in which drugs and devices are or may be dispensed or retailed, and to report any violations of sections 20-570 to 20-630, inclusive, or other laws relating to drugs and devices and violations of laws relating to pharmacy licenses, nonlegend drug permits, licenses of pharmacists and supervision of pharmacy interns and pharmacy technicians.

(b) The commissioner shall inspect correctional or juvenile training institutions throughout the state with respect to the handling of drugs , shall report violations of law and make recommendations for improvements in procedures to the authority responsible for the operation of the institution and shall other steps as may be necessary to ensure proper and adequate storage, handling and administration of drugs in such institutions. The commissioner may also inspect dispensing outpatient facilities and institutional pharmacies and take such steps as the commissioner considers appropriate to correct deficiencies found in such facilities or institutional pharmacies with respect to their operation.

(c) The commissioner shall inspect each retail pharmacy not less than once every four years and shall develop a methodology to sample prescriptions dispensed by retail pharmacies for compliance with state laws concerning the dispensing of prescriptions. Such methodology shall be based on the number of prescriptions received by such retail pharmacies.

Sec. 20-578. Information not to be disclosed. Exception. Information received by the department, the commission or the department of public health through filed reports or inspection or as otherwise authorized under chapters 418 and 420b and sections and sections 20-570 to 20-630, inclusive, shall not be disclosed publicly in such a manner as to identify individuals or institutions, , except in a proceeding involving the question of licensure or the right to practice. Nothing in this section shall be construed to prohibit the commissioner from disclosing information gained through the inspection of pharmacies and outlets holding permits for the sale of nonlegend drugs if the commissioner considers such disclosure to be in the interest of public health.

Sec. 20-579. Causes for suspension, revocation or refusal to issue or renew licenses and registrations. (a) The commission may refuse to authorize the issuance of a temporary permit to practice pharmacy, may refuse to authorize the issuance or renewal of a license to practice pharmacy, a license to operate a pharmacy or a registration of a pharmacy intern or pharmacy technician, and may revoke or suspend a license or temporary permit to practice pharmacy, a license to operate a pharmacy or a registration of a pharmacy intern or a pharmacy technician, and my assess a civil penalty of up to one thousand dollars or take other action permitted in subdivision (7) of section 21a-7 if the applicant or holder of the license, temporary permit or registration: (1) has violated a statute or regulation related to drugs, devices or the practice of pharmacy of this state, any

state of the United States, the United States, the District of Columbia, the Commonwealth of Puerto Rico, any territory or insular possession subject to the jurisdiction subject of the United States or a foreign jurisdiction; (2) has been convicted of violating any criminal statute relating to drugs, devices or the practice or pharmacy of this state, any state of the United States, the United States, the District of Columbia, the Commonwealth of Puerto Rico, any territory or insular possession subject to the jurisdiction of the united states or a foreign jurisdiction; (3) has been disciplined by, or is the subject of pending disciplinary action or an unresolved complaint before, the duly authorized pharmacy disciplinary agency of any sate of the United States, the United States, the District of Columbia, the Commonwealth of Puerto Rico, any territory or insular possession subject to the jurisdiction of the United States or a foreign jurisdiction; (4) has been refused a license or registration or renewal of a license or registration by any state of the United States, the United States, the District of Columbia, the Commonwealth of Puerto Rico, and territory or insular possession subject to the jurisdiction of the United States or a foreign jurisdiction based on grounds that are similar on which Connecticut could refuse to issue or renew such a license or registration ; (5) has illegally possessed, diverted, sold or dispensed drugs or devices; (6) abuses or excessively uses drugs, including alcohol; (7) has made false, misleading or deceptive representations to the public or commission; (8) has maintained exclusive telephone lines to, has maintained exclusive electronic communication with, or has exclusive access to computers located in offices of prescribing practitioners, nursing homes, clinics, hospitals or other health care facilities; (9) has substituted drugs or devices except as permitted in section 20-619; (10) has accepted, to return to regular stock, any drug already dispensed in good faith or delivered from a pharmacy, and exposed to possible and uncontrolled contamination or substitution; (11) has split fees for professional services, including a discount or rebate, with a prescribing practitioner or an administrator or owner of a nursing home, hospital or other healthcare facility; (12) has entered into an agreement with a prescribing practitioner or an administrator or owner of a nursing home, hospital or other healthcare facility for the compounding or dispensing of secret formula or coded prescriptions; (13) has performed or been a party to, a fraudulent or deceitful practice or transaction; (14) has presented to the commission a diploma, license or certificate illegally or fraudulently obtained, or obtained from a college or school of pharmacy not approved by the commission; (15) has performed incompetent or negligent work; (16) has falsified a continuing education document submitted to the commission or department or a certificate retained in accordance with the provisions of subsection (d) of section 20-600; (17) has permitted a person not licensed to practice pharmacy in this state to practice pharmacy in violation of section 20-605, to use a pharmacist license or pharmacy display document in violation of section 20-608, or to use words, displays or symbols in violation of section 20-609; or (18) has failed to maintain the entire pharmacy premises in a clean, orderly and sanitary condition.

(b) The commission may refuse to authorize the issuance of a temporary permit to practice pharmacy, may refuse to authorize the issuance or renewal of a license to practice pharmacy, a license to operate a pharmacy or a registration of a pharmacy intern or pharmacy technician, and may revoke or suspend a license or temporary permit to practice pharmacy, a license to operate a pharmacy, a registration of a pharmacy intern or a pharmacy technician, or take other action permitted in subdivision (7) of section 21a-7 if the commission determines that the applicant or holder of the license, temporary permit or registration has a condition including, but not limited to, physical illness or loss of skill or deterioration due to the aging process, emotional disorder or mental illness, abuse or excessive use of drugs or alcohol that would interfere with the practice of pharmacy, operation of a pharmacy or activities as a pharmacy intern or pharmacy technician, provided the commission may not, in taking action against a license, temporary permit or registration holder on the basis of such a condition, violate the provisions of section 46a-73 or 42 USC section 1132 of the federal Americans with Disabilities Act.

Sec. 20-580. Revocation or suspension of nonlegend drug permit. A permit to sell nonlegend drugs issued under section 43 of this act may be revoked or suspended by the commission for any violation of the provisions of chapter 419 or of sections 20-570 to 20-630, inclusive, or for any violation of any federal law concerning the sale or offer for sale of any nonlegend drug, or for the violation of any regulation concerning the sale or offer for sale of any nonlegend drugs.

Sec. 20-581. Penalty for violation of Pharmacy Practice Act. Exception. Any person who violates any provisions of sections 20-570 to 20-631, inclusive, and section 20-635 for the violation of which no other penalty has been provided shall be fined not more than five thousand dollars or imprisoned not more than five years or both. For purposes of this section, each instance of patient contact or consultation that is in violation of any provision of sections 20-570 to 20-631, inclusive, and section 20-635 shall be a separate offense. Failure to renew in a timely manner any license issued under said sections is not a violation for purposes of this section.

Sec. 20-582. Appeals of decisions of Commission of Pharmacy. Any person (1) holding a license, permit or registration under sections 20-570 to 20-630, who has been disciplined by the commission, or (2) who has been refused a license, permit or registration under said sections or refused a renewal of a license or permit under said sections ,may appeal as provided in section 4-183.

Sec. 20-583. Where appeals returnable. An appeal of a decision by the commission to discipline a person licensed to practice pharmacy or registered as a pharmacy intern or pharmacy technician, to refuse a person's application for a license to practice pharmacy or to refuse to register a person as a pharmacy intern or pharmacy technician shall be made returnable to the judicial district in which the person resides or, if the person does not reside in Connecticut, to the judicial district of Hartford-New-Britain. An appeal of a decision by the commission to discipline the holder of a pharmacy license or the holder of a permit to sell nonlegend drugs or to refuse a person's application for such a license or permit appeal shall be returnable to the judicial district in which the building or store is located for which the license or permit was sought or in which it was suspended or revoked. All appeals under the provisions of this section shall be treated as privileged and shall be assigned for trial and tried as soon as may be practicable.

Part II

Licensing of Pharmacists and Pharmacies. Pharmacy Interns

Sec. 20-590. Issuance of license to practice pharmacy; requirements. (a) The department shall, upon authorization of the commission, issue a license to practice pharmacy as a pharmacist to any individual provided the individual:

(1) Has submitted a written application on a form approved by the department;

(2) Has graduated from a college or school of pharmacy approved by the commission with a degree that was, at the time of graduation, an entry level professional pharmacy degree;

(3) Has the professional experience as a pharmacy intern required by regulations adopted by the commissioner, with the advice and assistance of the commission, in accordance with chapter 54;

(4) Has successfully passed the examination described under subsection(b) of this section;

(5) Is eighteen years of age or older at the time of the examination; and

(6) Has paid the examination fee specified in section 20-601.

(b) The examination for licensure required under subsection (a) of this section shall be given by the commission at least two times each year. The commission shall, with the approval of the

commissioner, determine the content and subject matter of each examination, and the place, time and date of administration of the examination.

(c) The Department of Consumer Protection shall, upon authorization of the commission, issue a temporary permit to practice pharmacy to an individual who: (1) Practices under the direct supervision of a licensed pharmacist; (2) has an application for reciprocity on file with the commission; (3) is a licensed pharmacist in good standing in a state or jurisdiction from which such state's pharmacy board or commission of pharmacy grants similar reciprocal privileges to pharmacists licensed in this state; and (4) has no actions pending against such individual's license with any state's pharmacy board or commission of pharmacy.

(d) A temporary permit to practice pharmacy shall expire at the time the individual with the temporary permit is licensed as a pharmacist in this state, or not later than three months from the date of issuance of such temporary permit, whichever occurs first. The Department of Consumer Protection shall not issue more than one temporary permit to practice pharmacy to an individual, but the commission, at its discretion, may authorize one three-month extension of the temporary permit.

Sec. 20-591. Graduates of foreign pharmacy schools. Regulations. (a) An individual who has graduated from a foreign school of pharmacy of pharmacy not approved by the commission may apply for a license to practice pharmacy under this section.

(b) The individual shall comply with the requirements of subdivisions (1), (2), (4), (5) and in lieu thereof of subsection (a) of section 20-590 and with regulations adopted as provided in subsection (c) of this section.

(c) The commissioner shall, with the advice and assistance of the commission, adopt regulations in accordance with chapter 54 of the general statutes concerning licensure of a pharmacist or an individual who has graduated from a foreign school of pharmacy. The regulations shall include a requirement that such a graduate pass a proficiency test for written and spoken english, a foreign pharmacy graduate equivalency examination and the examination described in subsection (b) of section 20-590.

Sec. 20-592. Licensure of individual who is a licensed pharmacist in another state or jurisdiction. (a) Any individual who is a licensed pharmacist in any other state of the United States, the District of Columbia, the Commonwealth of Puerto Rico or any territory or insular possession subject to the jurisdiction of the United States, may be licensed to practice pharmacy in this state in accordance with regulations adopted under sections 20-570 to 20-630, inclusive,in accordance with chapter 54.

Sec. 20-593. Pharmacist license certificate; expiration; renewal; fee; display document. (a) A license to practice pharmacy issued under the provisions of section 20-590 or under the provisions of section 20-591 or 20-592 and a license to practice pharmacy renewed pursuant to subsections (b) and (c) of this section shall be evidenced by a certificate issued by the department upon authorization of the Commission.

(b) A license to practice pharmacy shall expire annually and may be renewed upon completion of an application on a form approved by the department, payment of the fee set forth in section 20-601 and completion of continuing professional education, as required by sections 20-599 and 20-600.

(c) The commission shall not grant a renewal license to an applicant who has not held a license authorized by the commission within five years of the date of application unless the applicant has passed an examination satisfactory to the commission and has paid the fee required in section 20-601.

(d) In addition to the certificate of license to practice pharmacy issued under section (a) of this section, the department may issue a document suitable for display indicating that the individual has been issued a certificate of license to practice pharmacy.

Sec. 20-594. Pharmacy license; application; information required; issuance or renewal of license; expiration. Transfer of pharmacy to new location. (a) Except as limited by section 20-596, a pharmacist or any other person may apply to the commission for a pharmacy license or for renewal of a pharmacy license.

(b) The applicant shall disclose on the application the name and address of the applicant and the owner of the pharmacy, the name and street and mailing address of the pharmacy and the name, address and license number of the pharmacist who manages the pharmacy. The commissioner may, by regulation adopted with the advice and assistance of the commission, in accordance with chapter 54 , require such other information on the application as is necessary for the department to carry out its duties under sections 20-570 to 20-630, inclusive.

(c) The department shall, after receipt of an application under this section, (1) issue, on authorization of the commission, a pharmacy license to an applicant for a new pharmacy on payment of the fee required in section 20-601 and on satisfactory evidence to the commission that the pharmacy will be managed by a pharmacist and will be operated in accordance with the general statutes and regulations adopted by the commissioner in accordance with chapter 54, and (2) issue a renewal of a pharmacy license to an applicant on payment of the fee required in section 20-601.

(d) Pharmacy licenses shall expire annually. Pharmacy licenses may be renewed on application and payment of the fee required in section 20-601 for a period not to exceed one year.

(e) When a pharmacy license is transferred to a new location the pharmacy license for such pharmacy shall terminate. A pharmacy license that has been terminated under this subsection may be renewed under the provisions of subsection (d) of this section and on satisfactory evidence to the commission that the pharmacy will be managed by a pharmacist and will be operated in accordance with the general statutes and the regulations adopted by the commissioner in accordance with chapter 54.

Sec. 20-595. Pharmacy licenses held by corporations. Notice of change in officers or directors. Any corporation applying for a new or renewal pharmacy license under the provision of section 20-594 shall state in the application the names of the officers and directors of the corporation. Notice of any change in such officers or directors shall be given by the corporation to the commission within ten days after the change. Such notice shall be accompanied by the filing fee set forth in section 20-601. Any such corporation that fails to give notice of a change in the officers or directors of the corporation within ten days of the change shall pay the late fee required in section 20-601.

Sec. 20-596. Ownership of pharmacies by prescribing practitioners. (a) No prescribing practitioner, spouse of a prescribing practitioner, except a spouse who is a pharmacist, or dependent child of a prescribing practitioner shall have an ownership or investment interest in a pharmacy.

(b) The provisions of this section do not apply to a prescribing practitioner or spouse or dependent child of a prescribing practitioner (1) having an ownership or investment interest in a pharmacy prior to July 1, 1993, or (2) who inherits an ownership or investment interest in a pharmacy, or (3) who is not required to maintain professional liability insurance pursuant to section 20-11b, provided (A) if the prescribing practitioner reinstates any such professional liability insurance, the prescribing practitioner shall, within thirty days of doing so, notify the Commissioner of Public Health of such reinstatement and divest any interest the prescribing practitioner may have in any pharmacy or (B) if the interest is owned by the prescribing practitioner's spouse or dependent child, the spouse or child shall divest such interest in any pharmacy. Failure of the prescribing practitioner or the prescribing practitioner's spouse or dependent child to divest any such interest in

a pharmacy within thirty days shall result in the prescribing practitioner's license being suspended until such time as the prescribing practitioner or the prescribing practitioner's spouse or dependent child divests such interest in the pharmacy.

(c) As used in this section "ownership of investment interest" does not include ownership of investment securities by a prescribing practitioner, or the prescribing practitioner's spouse or dependent children in a publicly-held corporation that is traded on a national exchange or over-the-counter market, provided the investment securities held by the prescribing practitioner, the prescribing practitioner's spouse and the practitioner's dependent children, in aggregate, do not exceed one-half of one per cent of the total number of shares issued by the corporation.

Sec. 20-597. Pharmacy to be supervised and managed by pharmacist. Change in management, ownership or name of pharmacy. (a) No place of business may be operated as a pharmacy unless a pharmacy license has been issued for the place of business and unless it is under the direct supervision of a pharmacist on the premises, except that the commissioner, with the advice and assistance of the commission, shall adopt regulations, in accordance with chapter 54, that specify when a pharmacy may remain open for business during hours when a pharmacist is not present and directly supervising such pharmacy. Such regulation shall include, but not be limited to: (1) a provision requiring that the prescription department be closed and properly secured during times when a pharmacist is not present; (2) the minimum number of hours of operation applicable to the prescription department; (3) requirements for the physical security of the prescription department; (4) requirements for the physical security of legend drugs, controlled substances and legend devices stored in all areas of the pharmacy; and (5) a definition of the term "prescription department".

(b) In addition to the on-premises supervision of a pharmacy required in subsection (a) of this section, a pharmacy shall be managed by a pharmacist practicing at the pharmacy on a full-time basis who is listed as manager in the application for a pharmacy license made under section 20-594, or enrolled with commission under subsection (c) of this section. The managing pharmacist may also act as the supervising pharmacist. No pharmacist may manage more than one pharmacy at the same time.

(c) The person to whom a pharmacy license has been issued shall immediately notify the commission whenever the pharmacist who manages the pharmacy ceases such management and shall immediately enroll with the commission the name, address and license number of the pharmacist who assumes management of the pharmacy. The notice of change of management of a pharmacy required to be filed with the commission under this section shall be accompanied by the filing fee required in section 20-601. The pharmacist who ceases management of the pharmacy shall also immediately notify the commission of that fact.

(d) The person to whom a pharmacy license has been issued shall immediately notify the commission of a change in ownership of the pharmacy and of a change of name of the pharmacy. The notice shall be accompanied by the filing fee required in section 601. Any such person who fails to give the notice of a change of ownership or name of the pharmacy within ten days of the change shall pay the late fee required in section 601.

Sec. 20-598. Registration of pharmacy interns. (a) Each individual who is employed by or is serving under the supervision of a pharmacist in a pharmacy or institutional pharmacy for the purpose of obtaining the professional experience required under the provisions of section 20-590 shall register as a pharmacy intern with the commission at the time of commencing employment or service under such supervision. The applicant may not be registered as a pharmacy intern unless the applicant has successfully completed two years of college and is enrolled in a professional program at a school of college of pharmacy, accredited by the American Council of Pharmaceutical Education and approved by the Commission, or has completed the requirements for graduation from

such a school or college, or, if the applicant is a graduate from a foreign pharmacy school not approved by the commission, has passed a proficiency test for written and spoken english and a foreign pharmacy graduate equivalency examination. The application for registration shall be certified to, under oath, by the applicant.

(b) The fee required in section 20-601 shall accompany an application for registration and an identification number and card shall be issued by the commissioner to the applicant. The identification number and card shall be returned to the commission if the pharmacy intern does not complete the requirements for graduation from, or terminates enrollment at, an accredited and approved school or college of pharmacy.

Sec. 20-598a. Registration of pharmacy technicians. (a) No person shall act as a pharmacy technician unless registered with or certified with, the department.

(b) The department shall, upon authorization of the commission, register as a pharmacy technician any person who presents evidence satisfactory to the department that such person is qualified to perform, under the direct supervision of a pharmacist, routine functions in the dispensing of drugs that do not require the use of professional judgment. The qualifications for registration as a pharmacy technician under this section shall be in accordance with (1) the standards of an institutional pharmacy, a care-giving institution or a correctional or juvenile training institution, in the case of employment in any such pharmacy or institution, or (2) the standards established by regulation adopted by the commissioner in accordance with chapter 54, in the case of employment in a pharmacy. As used in this subsection, "direct supervision" means a supervising pharmacist (A) is physically present in the area or location where the pharmacy technician is performing routine drug dispensing functions, and (B) conducts in-process and final checks on the pharmacy technician's performance.

(c) The department shall, upon authorization of the commission, certify as a pharmacy technician any person who meets the requirements for registration as a pharmacy technician, pursuant to subsection (b) of this section, and who holds a certification from the Pharmacy Technician Certification board or any other equivalent pharmacy technician certification program approved by the department.

(d) The fee required by section 20-601, as amended, shall accompany an application for registration under this section. A registration as a pharmacy technician shall be valid for one year and may be renewed upon application and payment of the fee required by section 20-601, as amended.

Sec. 20-599. Continuing education: Definitions. As used in this section and section 20-600:

(1) **"Accredited continual professional education"** means any education of pharmacists which is designed to maintain professional competence in the practice of pharmacy and which is provided by an organization, institution or agency approved by the Connecticut Commission. Such education may include, but is not limited to, courses concerning (A) The social, economic, behavioral, administrative and managerial aspects of health care; (B) the properties and actions of drugs and dosage forms; (C) the etiology, characteristics, therapeutics and prevention of the disease states; (D) the pharmaceutical monitoring and management of patients; and (E) other areas other of information unique to specialized types of professional pharmacy practice;

(2) **"Certificate of continuing education"** means a document issued to a pharmacist by an, organization, institution or agency approved by the Commission which offers accredited continuing professional education which (A) certifies that the pharmacist has satisfactorily completed a specified number of continuing education units, and (B) bears the name of such organization,

institution or agency, the title of the program, the dates during which the program was conducted, the number of continuing education units satisfactorily completed and the signature of the director of such organization, institution or agency or the director's authorized agent;

(3) **"Continuing education unit"** means ten contact hours of participation in accredited continuing professional education;

(4) **"Contact hours"** means fifty to sixty minutes of participation in accredited continuing professional education;

(5) **"Retired pharmacist"** means a pharmacist who is at least sixty-two years of age and no longer actively engaged in the practice of pharmacy;

(6) **"Inactive license"** means a license that is issued, in the same manner and for the same fee as specified in this chapter for a license to practice pharmacy, to a retired pharmacist which license does not authorize the retired pharmacist to practice pharmacy and on which the word "inactive" is printed or stamped.

Sec. 20-600. Continuing education: Requirements; renewal of licenses; regulations. (a) Except as provided in subsections (b), (c), (f) and (g) of this section, the commission shall not authorize the department to renew a license to practice pharmacy as a pharmacist unless the pharmacist applying for the renewal submits a statement signed under the penalty of false statement that the pharmacist has satisfactorily completed no less than fifteen contact hours of accredited continuing professional education in the previous calendar year immediately preceding expiration of the license. Not less than five contact hours of the annual continuing education requirement shall be earned by attendance at a live presentation of an accredited continuing professional education program. At least one of the fifteen contact hours shall be on the subject matter of pharmacy law or drug law.

(b) The provisions of this section shall not apply to a pharmacist who applies for the first renewal of a license to practice pharmacy.

(c) A pharmacist submitting an application for renewal of a license to practice pharmacy, whose license has lapsed and who has not held a license authorized by the commission and issued by the department for more than two years, shall submit a statement signed under the penalty of false statement that the pharmacist has satisfactorily completed the requirements of this section in each of the years in the two-year period prior to the year of the application for renewal.

(d) A pharmacist who applies for renewal of a license to practice pharmacy shall retain all certificates of approved continuing education units for a period of no less than three years after the date on which such license is renewed. A pharmacist shall, upon the request of the department, and to satisfy the results of a random audit, make such certificates available to the department for purposes of verification.

(e) Continuing education units earned in one calendar year shall not be carried forward into the next calendar year for the purpose of fulfilling the subsequent year's accredited continuing professional education requirements for license renewal.

(f) A pharmacist who was unable to comply with the requirements of this section for reasons such as illness, incapacity or other extenuating circumstances may apply for a waiver of the requirements of this section or for an extension of time to fulfill the requirements of this section. A pharmacist who requests such a waiver or extension of time shall submit the request, in writing, to the department with the license renewal application. The department shall forward such a request to the commission for its consideration. If the commission waives the requirements of this section, the commission shall authorize the department to renew the license of such a pharmacist. If the commission extends the time for compliance with the requirements of this section, the commission shall authorize the department to renew the license, subject to the pharmacist's complying with the requirements of this section within the extended time period. If the pharmacist fails to comply with such requirements within the extended time period the commission shall revoke or suspend the license.

(g) The commission may authorize the department to waive the requirements of this section and renew the license of a retired pharmacist provided the license is designated as an inactive license. A retired pharmacist holding an inactive license shall be required to obtain thirty hours of continuing education, not less than ten hours of which shall be earned by attendance at a live presentation, and apply for and receive a license to practice pharmacy issued pursuant to sections 20-570 to 20-630, inclusive, before the retired pharmacist reenters the active practice of pharmacy.

(h) The commissioner, with the advice and assistance of the commission, may adopt regulations in accordance with chapter 54 to carry out the provisions of this section.

Sec. 20-601. Fees. The department of consumer protection shall collect the following nonrefundable fees:

(1) The fee for issuance of a pharmacist license shall be one hundred dollars, payable at the date of application for the license.

(2) The fee for applying to take the pharmacist license examination required in section 20-590 and in section 20-591 of this act is one hundred fifty dollars, payable at the date of application for the pharmacist license.

(3) The fee for renewal of a pharmacist license is the professional services fee for class A, as defined in section 33-1821. Before the commission grants a license to an applicant who has not held a license authorized by the commission within five years of the date of application, the applicant shall pay the fees required in subdivisions (1) and (2) of this section.

(4) The fee for issuance of a pharmacy license is six hundred dollars.

(5) The fee for renewal of a pharmacy license is one hundred fifty dollars.

(6) The late fee for an application for renewal of a license to practice pharmacy, a pharmacy license or a permit to sell nonlegend drugs is the amount set forth in section 21a-4.

(7) The fee for notice of a change in officers or directors of a corporation holding a pharmacy license is be thirty dollars for each pharmacy license held. A late fee for failing to give such notice within ten days of the change is twenty-five dollars in addition to the fee for notice.

(8) The fee for filing notice of a change in name, ownership or management of a pharmacy is forty-five dollars. A late fee for failing to give such notice within ten days of the change is twenty-five dollars in addition to the fee for notice.

(9) The fee for application for registration as a pharmacy intern is thirty dollars.

(10) The fee for application for a permit to sell nonlegend drugs is seventy dollars.

(11) The fee for renewal of a permit to sell nonlegend drugs is fifty dollars.

(12) The late fee for failing to notify the commission of a change of ownership, name or location of the premises of a permit to sell nonlegend drugs within five days of the change is ten dollars.

(13) The fee for the issuance of a nonresident pharmacy certificate of registration is six hundred dollars.

(14) The fee for renewal of a nonresident pharmacy certificate of registration is one hundred fifty dollars.

(15) The fee for application for registration as a pharmacy technician is fifty dollars.

(16) The fee for renewal of a registration as a pharmacy technician is twenty-five dollars.

(17) The fee for issuance of a temporary permit to practice pharmacy is one hundred dollars.

Sec. 20-602 to 20-604. Reserved for future use.

PART III

PRACTICE OF PHARMACY

Sec. 20-605. Practice of pharmacy without license prohibited. No individual may engage in the practice of pharmacy unless the individual holds a current license or temporary permit to practice pharmacy issued by the department.

Sec 20-606. Use of the title "pharmacist". A pharmacist who conforms to the regulations of the Commissioner, adopted with the advice and assistance of the commission in accordance with chapter 54, may have, use and exhibit the title " pharmacist" in the practice of pharmacy.

Sec. 20-607. Pharmacist certificate of license to be available for inspection. Each person practicing as a pharmacist, pharmacy intern or pharmacy technician shall at all times have available for inspection by an inspector of the department a current certificate of license or temporary permit to practice pharmacy or a current registration to act as a pharmacy intern or pharmacy technician.

Sec.20-608. Use of certificate of license or display document by unlicensed person prohibited. Penalties. A pharmacist who permits such pharmacist's certificate of license, temporary permit or display document to be used by an unlicensed person for unlawful use shall be fined one hundred dollars and shall be subject to other disciplinary proceeding within the authority of the Commission.

Sec. 20-609. Pharmacy license to be posted. Business which is not a pharmacy prohibited from using words, displays or symbols indicating it is a pharmacy. (a) A pharmacy license shall be conspicuously displayed within the pharmacy.

(b) Any person owning, managing or conducting any store, shop or place of business not being a pharmacy who exhibits within or upon the outside of such store, shop or place of business, or who includes in any advertisement the words "drug store", "pharmacy", "apothecary", "drug", "drugs", "medicine shop", or any combination of such terms or any other words, displays or symbols indicating that such store, shop or place of business is a pharmacy shall be fined not more than two hundred dollars or imprisoned not more than thirty days or both.

Sec. 20-610. Sale of drugs at retail (a) No legend drug, legend device or drugs listed in subsection (b) of this section may be dispensed or sold at retail except (1) in a pharmacy, (2) by a hospital licensed under sections 19a-490 to 19a-503, inclusive, to an employee of the hospital when prescribed by a prescribing practitioner for the employee or the employee's spouse or dependent children, or (3) by such hospital to a retiree of such hospital or the retiree's spouse in accordance with the retiree's retirement or pension plan.

(b) The following drugs may not be sold at retail except as permitted in subsection (a) of this section: (1) injectable or ingestible antibiotics; (2) injectable biologicals; (3) sulfonamides and their compounds which are designed to be taken into the stomach for systemic action; (4) injectable or ingestible corticosteroids; or (5) camphorated tincture of opium.

(c) Any person who violates any provision of this section shall be fined not less than one hundred nor more than five hundred dollars.

Sec. 20-611. Advertising legend drug prices. A pharmacist or any person holding a pharmacy license (1) may advertise the price of any legend drug sold at retail based upon the prescription of a prescribing practitioner, provided, each such advertisement shall clearly state the period during which the advertised price or prices shall remain in effect and shall not contain any statement indicating that the advertised price or prices are subject to change without notice; and (2) shall disclose upon request, the price of any such legend drug to any prospective purchaser.

Sec. 20-612. Only a pharmacy may accept prescription for dispensing. Subject to the provisions of subsection (d) of section 20-614, as amended by this act, only a pharmacy shall accept a prescription for dispensing. No employee, personnel or owner of a place of business or establishment not licensed as a pharmacy may accept a prescription for transfer to or for collection for a pharmacy.

Sec. 20-613. Dispensing of drug or legend device pursuant to prescription only; exception. Emergency dispensing or drug or device in care-giving, correctional or juvenile training institutions; regulations. Pharmacy technicians. Prescribing practitioner authorized to dispense own prescription, when. (a) Except as provided in subsection (b) and (d) of this section, a drug or legend device may be dispensed pursuant to a prescription only in a pharmacy or institutional pharmacy by a pharmacist or by a pharmacy intern when acting under the direct supervision of a pharmacist, or by an individual holding a temporary permit.

(b) In care-giving institutions and correctional or juvenile training institutions in emergency situations when the pharmacist is not available for the dispensing of drugs or devices from the institutional pharmacy, the prescription shall be reviewed by the nursing supervisor or a physician before administration of the drug or device and recorded with the pharmacist in its original form or a copy thereof. After the required review in such emergency situations, the person authorized by the institution may dispense drugs and devices from the institutional pharmacy pursuant to regulations adopted by the commissioner, with the advice and assistance of the Commission.

(c) A pharmacy technician in a pharmacy or an institutional pharmacy may assist, under the direct supervision of a pharmacist, in the dispensing of drugs and devices. A person whose license to practice pharmacy is under suspension or revocation shall not act as a pharmacy technician.

(d) Nothing in sections 20-570 to 20-630, inclusive, shall prevent a prescribing practitioner from dispensing the prescribing practitioner's own prescriptions to the prescribing practitioner's own patients when authorized within the scope of his own practice and when done in compliance with sections 20-14c to 20-14g, inclusive.

Sec. 20-614. Prescriptions: Form and content. (a) A prescription shall be transmitted in either an oral, written or electronic manner to a pharmacy.

(b) Whenever a pharmacy or an institutional pharmacy in a hospital dispensing a drug or device that is prescribed for outpatient use or dispensing a drug or device that is prescribed for an employee of the hospital or for the employee’s spouse or dependent children, receives and oral or electronically-transmitted prescription, except for a controlled drug, as defined in section 21a-240, the pharmacist or pharmacy intern shall, not later than the end of the business day when the prescription was received, record the prescription on a prescription form or computerized printed record including (1) The name and address of the prescribing practitioner; (2) the date of the prescription; (3) the name, dosage form, strength, where applicable, and the amount of the drug prescribed; (4) the name and address of the patient or, for veterinary prescriptions, the name and address of the owner and the species of the animal; (5) the directions for use; (6) any required cautionary statements; and (7) the number of times the prescription may be refilled, including the use if refill terms “PRN” and “ad lib” in lieu of a specific number of authorized refills.

(c) A written prescription shall bear: (1) the written signature of the prescribing practitioner or shall comply with the requirements of section 19a-509c; (2) the address of the practitioner; (3) the date of the prescription; (4) the name, dosage form, strength, where applicable, and amount of drug prescribed; (5) the name and address of the patient or, for veterinary prescriptions, the name and address of the owner and the species of the animal; (6) the directions for use; (7) any required cautionary statements; and (8) the number of times the prescription may be refilled, including the use of the refill terms "PRN" and "ad lib" in lieu of a specific number of authorized refills. No written prescription form for a schedule II substance may contain an order for any other legend drug or device.

(d) (1) As used in this subsection, "electronic data intermediary" means an entity that provides the infrastructure that connects the computer systems or other electronic devices utilized by prescribing practitioners with those used by pharmacies in order to facilitate the secure transmission of electronic prescription orders, refill authorization requests, communications and other patient care information between such entities.

(2) An electronic data intermediary may transfer electronically transmitted data between a prescribing practitioner licensed and authorized to prescribe and a pharmacy of the patient's choice, licensed pursuant to chapter 400j or licensed under the laws of any other state or territory of the United States. Electronic data intermediaries shall not alter the transmitted data except as necessary for technical processing purposes. Electronic data intermediaries may archive copies of only that electronic data related to such transmissions necessary to provide for proper auditing and security of such transmissions. Such data shall only be maintained for the period necessary for auditing purposes. Electronic data intermediaries shall maintain patient privacy and confidentiality of all archived information as required by state and federal law.

(3) No electronic data intermediary shall operate without the approval of the Commissioner of Agriculture and Consumer Protection. An electronic data intermediary seeking approval shall apply to the Commission of Pharmacy in the manner prescribed by the commissioner. The commissioner, with the advice and assistance of the commission, shall adopt regulations, in accordance with the provisions of chapter 54 of the general statutes, to establish criteria for the approval of electronic data intermediaries, including requirements for (A) the procedures to be used for the transmission and retention of prescription data by an intermediary and (B) mechanisms to be used by an intermediary to safeguard the confidentiality of such data.

Sec. 20-615. Prescription: Pharmacy to assign serial number and maintain records. Transfer of records to another pharmacy. (a) An institutional pharmacy dispensing a drug in circumstances described in subsection (g) of this section and a pharmacy shall assign and record a serial number to each prescription that it fills and shall keep all written prescriptions and the record of oral and electronically-transmitted prescriptions required in section 20-614 in numerical order in a suitable file or ledger for period of not less than three years. The records shall indicate the date of filling, the name and address of the prescribing practitioner, the name and address of the patient or the name and address of the owner of an animal for whom the prescription was written and the species of the animal and the initials of the pharmacist who dispensed the drug.

(b) A refill of a prescription shall be recorded on the face or back of the original prescription.

(c) Records maintained under this section shall be made available for inspection upon request of any authorized agent of the commissioner or other person authorized by law.

(d) When a pharmacy closes temporarily or permanently, the pharmacy shall, in the interest of public health, safety and convenience, make its complete prescription records immediately available to a nearby pharmacy and post a notice of this availability on the window or door of the closed pharmacy.

(e) Any violation of this section shall be punishable as provided in section 20-185, as amended by section 12 of this act.

(f) This section shall not apply to records maintained in accordance with regulations adopted pursuant to section 20-576 or 21a-244, to the extent such regulations are inconsistent with this section.

(g) When an institutional pharmacy in a hospital dispenses a drug or device for outpatient use or dispenses a drug or device that is prescribed for an employee of the hospital or for the employee's spouse or dependent children, the provisions of subsections (a), (b), (c) and (e) of this section shall apply.

Sec. 20-616. Prescription: Refills. (a) Except as provided in subsection (b) of this section, a prescription may be refilled only upon the written, oral or electronically-transmitted order of a prescribing practitioner.

(b) A pharmacist may exercise his professional judgment in refilling a prescription, that is not for a controlled drug, as defined in section 21a-240, without the authorization of the prescribing practitioner provided (1) the pharmacist is unable to contact such practitioner after reasonable effort, (2) failure to refill the prescription might result in an interruption of a therapeutic regimen or create patient suffering, and (3) the pharmacist informs the patient or representative of the patient at the time of dispensing that the refill is being provided without such authorization and informs the practitioner at the earliest reasonable time that authorization of the practitioner is required for future refills. Prescriptions may be refilled once pursuant to this subsection for a quantity of drug not to exceed a seventy-two hour supply.

(c) Any prescription that is not for a controlled drug, as defined in section 21a-240, may be transferred orally or electronically between pharmacies, provided:

(1) The prescribing practitioner has authorized the original prescription to be refilled in accordance with subsection (a) of this section;

(2) The pharmacist transferring the prescription shall cancel the original prescription in such pharmacist's records and shall indicate in such records the name of the pharmacy to which the prescription is transferred and the date of the transfer, provided, such cancellation shall not be required in the case of any transfer between pharmacies which electronically access the same prescription records and utilize the same computer or other electronic prescription transfer system; and

(3) The pharmacist receiving the prescription shall indicate in such pharmacist's records, in addition to any other information required by law, (A) the fact that the prescription has been transferred and the names of the transferring pharmacy and pharmacist, (B) the date of issuance and the prescription number of the original prescription, (C) the date the original prescription was first dispensed, (D) the number of refills authorized by the original prescription and the complete refill record for the prescription as of the date of the transfer, and (E) the number of valid refills remaining as of the date of the transfer.

Sec. 20-617. Prescriptions: Notation of drug quantities required on labels. Each pharmacist shall include on the label of each prescription container: (1) The quantity of prescribed drug placed therein in addition to any other information required by law; and (2) a prominently printed expiration date based upon the manufacturer's recommended conditions of use and storage that can be read and understood by the ordinary individual. The expiration date required pursuant to subdivision (2) of this section shall be no later than the expiration date determined by the manufacturer.

Sec. 20-618. Repackaged drugs not considered misbranded, when. Notwithstanding the provisions of section 21a-106 Concerning misbranding of drug or devices, a drug shall not be

considered misbranded when repackaged by a pharmacy or an institutional pharmacy into stock packages for use within the pharmacy or the institutional pharmacy, provided the stock packages contain a label indicating the drug's name, strength, lot number, manufacturer and expiration date, if any.

Sec. 20-619. Substitution of generic drugs. Regulations. (a) For the purposes of section 20-679 and this section:

(1) **"Brand name"** means the proprietary or trade name selected by the manufacturer and placed upon a drug product, its container, label or wrapping at the time of packaging;

(2) **"Generic name"** means the established name designated in the official United States Pharmacopoeia/National Formulary, official Homeopathic Pharmacopoeia of the United States, or official United States Adopted Names or any supplement to any of them;

(3) **"Therapeutically equivalent"** means drug products that are approved under the provisions of the federal Food, Drug and Cosmetic Act for interstate distribution and that will provide essentially the same efficacy and toxicity when administered to an individual in the same dosage regimen; and

(4) **"Dosage form"** means the physical formulation in which the product is intended, manufactured and made available for use, including, but not limited to, tablets, capsules, oral solutions, aerosol, inhalers, gels, lotions, creams, ointments, transdermals and suppositories, and the particular form of any physical formulation or medium that uses a specific technology or mechanism to control, enhance or direct the release, targeting, systemic absorption, or any other delivery of a dosage regimen in the body.

(b) Except as limited by subsections (c) and (e) of this section, unless the purchaser instructs otherwise, the pharmacist may substitute the same generic drug product with the same strength, quantity, dose and dosage form as the prescribed drug product which is, in the pharmacist's professional opinion, therapeutically equivalent. When the prescribing practitioner is not reasonable available for consultation and the prescribed drug does not use a unique delivery system technology, the pharmacist may substitute and oral tablet, capsule or liquid form of the prescribed drug as long as the form dispensed has the same strength, dose and dose schedule and is therapeutically equivalent to the drug prescribed. The pharmacist shall inform the patient or a representative of the patient, and the practitioner of the substitution at the earliest reasonable time.

(c) A prescribing practitioner may specify in writing or by a telephonic or other electronic communication that there shall be no substitution for the specified brand name drug product in any prescription, provided (1) in any prescription for a Medicaid, state-administered general assistance, general assistance or ConnPACE recipient, such practitioner specifies the basis on which the brand name drug product and dosage form is medically necessary in comparison to a chemically equivalent generic drug product substitution, and (2) the phrase "BRAND MEDICALLY NECESSARY", shall be in the practitioner's handwriting on the prescription form or on an electronically-produced copy of the prescription form or, if the prohibition was communicated by telephonic or other electronic communication that did not reproduce the practitioner's handwriting, a statement to that effect appears on the form. The phrase "BRAND MEDICALLY NECESSARY" shall not be preprinted or stamped or initialed on the form. If the practitioner specifies by telephonic or other electronic communication that did not reproduce the practitioner's handwriting that there shall be no substitution for the specified brand name drug product in any prescription for a Medicaid, state-administered general assistance, general assistance or ConnPACE recipient, written certification in the practitioner's handwriting bearing the phrase "BRAND MEDICALLY NECESSARY" shall be sent to the dispensing pharmacy within ten days.

(d) Each pharmacy shall post a sign in a location easily seen by patrons at the counter where prescriptions are dispensed stating that, "this pharmacy may be able to substitute a less expensive

drug product which is therapeutically equivalent to the one prescribed by your doctor unless you so not approve." The printing on the sign shall be in block letters not less than one inch in height.

(e) A pharmacist may substitute a drug product under subsection (b) of this section only when there will be a savings in cost passed on to the to the purchaser. The pharmacist shall disclose the amount of the savings at the request of the patient.

(f) Except as provided in subsection (g) of this section, when a pharmacist dispenses a substitute drug product as authorized by subsection (b) of this section, the pharmacist shall label the prescription container with the name of the dispensed drug product. If the dispensed drug product does not have a brand name, the prescription label shall indicate the generic name of the drug product dispensed along with the name of the drug manufacturer or distributor.

(g) A prescription dispensed by a pharmacist shall bear upon the label the name of the drug in the container unless the prescribing practitioner writes "do not label," or words of similar import, on the prescription or so designates in an oral or electronic transmission of the prescription.

(h) Neither the failure to instruct by the purchaser as provided in subsection (b) of this section nor the fact that a sign has been posted as provided in subsection (d) of this section shall constitute a defense on the part of a pharmacist against a suit brought by any such purchaser.

(i) The commissioner, with advice and assistance of the commission shall adopt regulations, in accordance with chapter 54, to carry out the provisions of this section.

Sec. 20-620. Pharmacist's duty toward Medicaid recipients: To obtain, record and maintain pertinent patient information about the recipient; to undertake a review of the drugs previously dispensed to the recipient and to offer to discuss the drugs to be dispensed and to counsel the recipient on their correct usage. Exception. (a) Prior to or simultaneously with dispensing a prescription in accordance with sections 17b-260 to 17b-262, inclusive, and 17b-264 to 17b-285, inclusive, a pharmacist or the designee of the pharmacist shall make a reasonable effort to obtain, record and maintain, in a manner deemed appropriate by the pharmacist, the following information regarding the individual receiving such prescription: (1) name, address, telephone number, date of birth or age and gender; (2) individual history where significant, including disease states, known allergies and drug reactions; (3) a comprehensive list of drugs and relevant devices dispensed by the pharmacy within the last one hundred eighty days and (4) the pharmacist's comments relevant to the individual's drug therapy.

(b) Prior to or simultaneously with dispensing a drug to individuals eligible for benefits in accordance with sections 17b-260 to 17b-262, inclusive, and 17b-264 to 17b-285, inclusive, a pharmacist shall undertake a review of drugs dispensed to the individual by the pharmacy during the previous one hundred eighty days. The review shall include screening for potential drug therapy problems due to therapeutic duplication, a contraindication between a drug and a disease, the interaction of one drug with another, incorrect drug dosage or duration of drug treatment, the interaction of a drug and an allergy, clinical abuse or misuse and any other significant clinical issues relating to the appropriate use of drugs. Such review shall be based upon current standards and information consistent with that provided in the following resources: The American Hospital Formulary Service Drug Information, the United States Pharmacopoeia Drug Information, the American Medical Association Drug Evaluations, and the peer-reviewed medical literature.

(c) Prior to or simultaneously with dispensing drugs to individuals eligible for benefits in accordance with sections 17b-260 to 17b-262, inclusive, and 17b-264 to 17b-285, inclusive, a pharmacist shall, whenever practicable, offer in person to discuss the drugs to be dispensed and to counsel the client on its usage, except when the person obtaining the prescription is other than the person named on the prescription form or the pharmacist determines it is appropriate to make such offer in writing. Any such written offer shall include an offer to communicate with the client either in person at the pharmacy or by telephone.

(d) The discussion and counseling offered in accordance with subsection (c) of this section shall include information deemed significant by the pharmacist based upon the findings of the review conducted in accordance with subsection (b) of this section, including (1) the name and description of the drug; (2) dosage form, dosage, route of administration and duration of drug therapy; (3) special directions and precautions for preparation, administration and use by the patient; (4) common severe side or adverse effects or interactions and therapeutic contraindications or precautions which the pharmacist deems relevant; (5) techniques for self-monitoring drug therapy; (6) proper storage; (7) prescription refill information; and (8) action to be taken in the event of a missed dose or adverse reaction.

(e) Nothing in this section shall be construed as requiring a pharmacist to provide counseling or gather information when an individual receiving benefits refuses such counseling or refuses or is unable to provide the information requested. The pharmacist shall document the provision of counseling, a refusal by or the inability of the patient to accept counseling or a refusal by the patient to give information. Records kept pursuant to this subsection shall be maintained for the same length of time as prescription records are maintained pursuant to section 20-615.

(f) The provisions of subsections (c) and (d) of this section shall not apply to a drug dispensed to a patient of a nursing home which is in compliance with the requirements of 42 CFR 483.60.

Sec. 20-621. Relabeling and dispensing of parenteral medication in hospital and nursing home pharmacies: When allowed. A pharmacist practicing in a hospital pharmacy or nursing home pharmacy may relabel and dispense to a registered inpatient, parenteral medication, except controlled substances, dispensed for another registered patient by a licensed pharmacy if the following requirements are met: (1) The original medication order for the drug is discontinued; (2) the medication is in an unopened tamper-evident package; (3) the medication is not expired; (4) the original patient is not charged for the medication; and (5) upon receipt of the medication by the facility from the licensed pharmacy, it is processed through the hospital's pharmacy or nursing home pharmacy.

Sec. 20-622. Licensed practitioners may authorize medication to be dispensed from a hospital emergency room. When the therapeutic needs of a patient require that medication be initiated immediately and the services of a licensed pharmacy are not available within a five-mile radius of a hospital emergency room, a person associated with such hospital authorized to dispense medication may dispense up to a twenty-four hour supply of medication, excluding controlled substances, to such patient. Such dispensing shall be authorized by a verbal order of a licensed practitioner. For purposes of this section "licensed practitioner" means a physician on the staff of such hospital or other practitioner associated with such hospital who has examined such patient and determined the patient's therapeutic needs.

Sec. 20-623. Sale of nonlegend drugs. Labels, packaging and contents. Penalty. (a) No nonlegend drug may be sold at retail except at a pharmacy or at a store that has obtained from the Commission a permit to sell nonlegend drugs. Nonlegend drugs shall be labeled and packaged in accordance with state and federal law.

(b) Any person who violates any provision of this section shall be fined not less than one hundred dollars nor not more than five hundred dollars.

Sec. 20-624. Permit to sell nonlegend drugs. (a) Any person may apply to the commission for a permit to sell nonlegend drugs.

(b) The commission may, in accordance with regulations adopted under sections 20-570 to 20-630, inclusive, and on payment of the fee required in section 20-601, issue to an applicant a permit to sell nonlegend drugs for one year.

(c) A permit that has expired under this section may be renewed, on application and payment of the renewal fee and any late fee required in section 20-601.

(d) The holder of a permit to sell nonlegend drugs shall notify the commission of a change of ownership, name or location of the permit premises. Any holder who fails to notify the commission within five days of the change shall pay the late fee required in section 20-601.

(e) Any nonlegend drug permit issued by the commission pursuant to this section is nontransferable.

Sec. 20-625. Nonlegend veterinary drugs. Nothing in sections 20-570 to 20-630 shall be construed to prohibit the sale of veterinary drugs that are nonlegend drugs by any person who holds a permit to sell nonlegend drugs.

Sec. 20-626. Confidentiality of pharmacy records. (a) No Pharmacist or pharmacy shall reveal any records or information concerning the nature of pharmaceutical services rendered to a patient without the oral or written consent of the patient or the patient's agent. If a patient or a patient's agent gives oral consent to release records or information, the pharmacist shall promptly record, in writing or in electronic data base form, the oral consent by listing the patient's name, the name of the patient's agent, if applicable, the date and the nature of the records or information released.

(b) Notwithstanding subsection (a) of this act, a pharmacist or pharmacy may provide pharmacy records or information to the following: (1) The patient; (2) the prescribing practitioner or a pharmacist or another prescribing practitioner presently treating the patient when deemed medically appropriate; (3) a person registered or licensed pursuant to chapter 378 who is acting as an agent for a prescribing practitioner that is presently treating the patient or a person registered or licensed pursuant to Chapter 378 of the general statutes providing care to the patient in a hospital; (4) third party payors who pay claims for pharmaceutical services rendered to a patient or who have a formal agreement or contract to audit any records or information in connection with such claims; (5) any government agency with statutory authority to review or obtain such information; (6) any individual, the state or federal government or any agency thereof or court pursuant to a subpoena; and (7) any individual, corporation, partnership or legal entity which has a written agreement with a pharmacy to access the pharmacy's database provided the information accessed is limited to data which does not identify specific individuals.

Sec. 20-627. Nonresident pharmacy. Definitions. Certificate of registration. Requirements. (a) As used in sections 20-627 to 20-630, inclusive,: "Nonresident Pharmacy" means any pharmacy located outside this state which ships, mails or delivers, in any manner, legend devices or legend drugs, as defined in subdivisions (13) and (14) of section 20-184a respectively, into this state pursuant to a prescription order.

(b) A nonresident pharmacy shall be registered with the department, upon approval of the commission, and shall:

(1) Disclose annually in a report to the commission the location, names and titles of all principal corporate officers, if applicable, and all pharmacists who are dispensing drugs or devices to residents of this state. A nonresident pharmacy shall file an additional report within thirty days after any change of office, corporate officer or pharmacist.

(2) Submit a statement that the nonresident pharmacy complies with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is licensed as well as comply with all requests for information made by the commission pursuant to this section.

(3) Maintain at all times, a valid unexpired license, permit or registration to conduct such pharmacy in compliance with the laws of the state in which the nonresident pharmacy is located.

(4) Before receiving a certificate or registration from the department of consumer protection, submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located.

(c) A nonresident pharmacy shall, during its regular hours of operation, but not less than six days per week, and for a minimum of forty hours per week, provide a toll-free telephone number to facilitate communication between patients in this state and a pharmacist at such nonresident pharmacy who has access to the patient's records. Such toll-free telephone number shall be disclosed on a label affixed to each container of drugs dispensed to patients in this state.

Sec. 20-628. Shipping, mailing or delivering legend devices or drugs. No nonresident pharmacy shall engage in the business of shipping, mailing or delivering, legend devices or legend drugs in this sate unless such nonresident pharmacy has been issued a certificate of registration by the commission and has paid the fee for issuance or renewal of such certificate of registration required in section 20-601. Applications for a certificate of registration as a nonresident pharmacy shall be made on a form furnished by the commission. The commission may require such information as it deems reasonably necessary to carry out the purpose of this section.

Sec. 20-629. Suspension or revocation of certificate. (a) The commission of pharmacy may deny, revoke or suspend and certificate of registration as a non resident pharmacy for failure to comply with any requirement of sections 20-627 to 20-630, inclusive.

(b) The commission may deny, revoke or suspend any certificate of registration as a nonresident pharmacy for conduct which causes serious bodily or serious psychological injury to a resident of this state if the commission has referred the matter to the regulatory or licensing agency in the state in which the nonresident pharmacy is located and such regulatory or licensing agency agency fails to (1)initiate an investigation within forty-five days of referral, (2) complete its investigation within one hundred twenty days of referral, (3) resolve the referral through formal agreement, settlement or decision within one hundred eighty days, or (4) initiate disciplinary proceedings wen such proceedings are determined to be necessary in the judgment of the regulatory or licensing agency in the state in which the nonresident pharmacy is located.

Sec. 20-630. Advertising. It shall be unlawful for any nonresident pharmacy which has not been issued a certificate of registration pursuant to section 20-628 to advertise its services in this state, or for any person who is a resident of this state to advertise the services of a nonresident pharmacy which has not received a certificate of registration from the commission, with the knowledge that the advertisement will or is likely to induce members of the public in this state to use the pharmacy to dispense prescription orders.

Sec. 20-631. Collaborative drug therapy management agreements between pharmacist employed by a hospital and one or more physicians. Regulations. (a)(1) One or more pharmacists licensed under this chapter , who are determined eligible in accordance with subsection (c) of this section, and employed by a hospital may enter into a written protocol-based collaborative drug therapy management agreement with one or more physicians licensed under chapter 370 to manage the drug therapy of individual patients receiving inpatient services in a hospital licensed under chapter 368v in accordance with subsections (b) to (d), inclusive, of this section and subject to the approval of the hospital. Each patient's collaborative drug therapy management shall be governed by a written protocol specific to that patient established by the treating physician in consultation with the pharmacist.

(2) One or more pharmacists licensed under this chapter who are determined eligible in accordance with subsection (c) of this section and employed by or under contract with a nursing home facility, as defined in section 19a-521, may enter into a written protocol-based collaborative drug therapy management agreement with one or more physicians licensed under chapter 370 to manage the drug therapy of individual patients receiving services in a nursing home facility, in accordance with subsections (b) to (d), inclusive, of this section and subject to the approval of the nursing home facility. Each patient's collaborative drug therapy management shall be governed by a written protocol specific to that patient established by the treating physician in consultation with the pharmacist. Each such protocol shall be reviewed and approved by the active organized medical staff of the nursing home in accordance with the requirements of section 19-13-D8t(i) of the Public Health Code.

(3) One or more pharmacists licensed under this chapter who are determined eligible in accordance with subsection (c) of this section and employed by or under contract with a hospital licensed under chapter 368v may enter into a written protocol-based collaborative drug therapy management agreement with one or more physicians licensed under chapter 370 to manage the drug therapy of individual patients receiving outpatient hospital care or services for diabetes, asthma, hypertension, hyperlipidemia, osteoporosis, congestive heart failure or smoking cessation, including patients who qualify as targeted beneficiaries under the provisions of Section 1860D-4(c)(2)(A)(ii) of the federal Social Security Act, in accordance with subsections (b) to (d), inclusive, of this section and subject to the approval of the hospital. Each patient's collaborative drug therapy management shall be governed by a written protocol specific to that patient established by the treating physician in consultation with the pharmacist.

Sec. 2. Not later than January 1, 2006, the Commissioner of Consumer Protection, in consultation with the Commission of Pharmacy, shall establish and operate a two-year pilot program to allow not more than ten pharmacists licensed under chapter 400j of the general statutes who are determined eligible in accordance with subsection (c) of this section and employed by or under contract with a licensed community pharmacy, to enter into a written protocol-based collaborative drug therapy management agreement with one or more physicians licensed under chapter 370 of the general statutes, to manage the drug therapy of individual patients receiving drug therapy for diabetes, asthma, hypertension, hyperlipidemia, osteoporosis, congestive heart failure or smoking cessation, including patients who qualify as targeted beneficiaries under the provisions of Section 1860D-4(c)(2)(A)(ii) of the federal Social Security Act, in accordance with subsections (b) to (d), inclusive, of this section and subject to the approval of the licensed community pharmacy. Each patient's collaborative drug therapy management shall be governed by a written protocol specific to that patient established by the treating physician in consultation with the pharmacist.

(b) A collaborative drug therapy management agreement may authorize a pharmacist to implement, modify or discontinue a drug therapy that has been prescribed for a patient, order associated laboratory tests and administer drugs, all in accordance with a patient-specific written protocol. Each protocol developed, pursuant to the collaborative drug therapy management agreement, shall contain detailed direction concerning the actions that the pharmacist may perform for that patient. The protocol shall include, but need not be limited to, (1) the specific drug or drugs to be managed by the pharmacist, (2) the terms and conditions under which drug therapy may be implemented, modified or discontinued, (3) the conditions and events upon which the pharmacist is required to notify the physician, and (4) the laboratory tests that may be ordered. All activities performed by the pharmacist in conjunction with the protocol shall be documented in the patient's medical record. The pharmacist shall report to the physician through oral, written or electronic manner regarding the implementation, administration, modification or discontinuation of a drug therapy that has been prescribed for a patient not later than twenty-four hours after such implementation, administration, modification or discontinuation. The

collaborative drug therapy management agreement and protocols shall be available for inspection by the Departments of Public Health and Consumer Protection. A copy of the protocol shall be filed in the patient's medical record.

(c) In order to be selected for participation in the program, a pharmacist shall be responsible for demonstrating, in accordance with this subsection, the competence necessary for participation in each drug therapy management agreement into which such pharmacist may enter. The pharmacist's competency shall be determined by the Commission of Pharmacy using criteria based on the continuing education requirements of sections 20-599 and 20-600 of the general statutes.

(d) The Commissioner of Consumer Protection and the Commission of Pharmacy shall evaluate the pilot program established under this section and shall submit a report of the commissioner's findings and recommendations to the joint standing committees of the General Assembly having cognizance of matters relating to public health, human services and general law, not later than December 31, 2008, in accordance with the provisions of section 11-4a of the general statutes. Such report shall include an evaluation of the data collected with respect to improved medication management and cost savings, based on patient outcomes.

(e) Records or information collected or maintained pursuant to this section shall not be disclosed pursuant to subsection (a) of section 1-210 of the general statutes for a period of six months from the date such records or information were created or collected and shall not be subject to subpoena or discovery or introduced into evidence in any judicial or administrative proceeding except as otherwise specifically provided by law.

(f) For purposes of this section, "community pharmacy" means a pharmacy licensed under section 20-594 of the general statutes that stores and dispenses legend drugs, as defined by section 20-571 of the general statutes, and legend devices, as defined by said section 20-571, and from which related pharmaceutical care services are provided, primarily to noninstitutionalized patients living in a community setting.

Sec. 20-632 to 20-639. Reserved for future use.

Part IV

Prescription Error Reporting

Section 20-635. Prescription error reporting. Definitions. Informational signs and statements. Regulations. (a) As used in this section:

(1) "Dispensing" means those acts of processing a drug for delivery or for administration for a patient pursuant to a prescription consisting of: (A) Comparing the directions on the label with the directions on the prescription to determine accuracy; (B) the selection of the drug from stock to fill the prescription; (C) the counting, measuring, compounding or preparation of the drug; (D) the placing of the drug in the proper container; (E) the affixing of the label to the container; and (F) the addition to a written prescription of any required notations;

(2) "Drug" means (A) an article recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States or official National Formulary, or any supplement to any of them, (B) an article intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans, (C) an article, other than food, intended to affect the structure or any function of the body of humans;

(3) "Pharmacy" means a place of business where drugs may be sold at retail and for which a pharmacy license has been issued to an applicant under the provisions of section 20-594 of the general statutes. For the purposes of this section, "pharmacy" shall include any areas of an institutional pharmacy where prescription drugs are dispensed to outpatients, employees and retirees;

(4) "Prescribing practitioner" means an individual licensed by the state of Connecticut, any other state of the United States, the District of Columbia, the Commonwealth of Puerto Rico or any territory or insular possession subject to the jurisdiction of the United States who is authorized to issue a prescription within the scope of the individual's practice;

(5) "Prescription" means a lawful order of a prescribing practitioner transmitted either orally, in writing or by electronic means for a drug for a specific patient; and

(6) "Prescription error" means an act or omission of clinical significance relating to the dispensing of a drug that results in or may reasonably be expected to result in injury to or death of a patient.

(b) Each pharmacy shall display a sign concerning the reporting of prescription errors in a conspicuous location visible to consumers of prescription drugs. The sign shall measure a minimum of eight inches in height and ten inches in length and the lettering shall be in a size and style that allows such sign to be read without difficulty by consumers standing at the pharmacy prescription department distribution counter. The sign shall bear the following statement: "If you have a concern that an error may have occurred in the dispensing of your prescription you may contact the Department of Consumer Protection, Drug Control Division, by calling (Department of Consumer Protection telephone number authorized pursuant to section 21a-2 of the general statutes)".

(c) Each pharmacy that dispenses a prescription to a consumer shall include the following printed statement on the receipt or in the bag or other similar packaging in which the prescription is contained: "If you have a concern that an error may have occurred in the dispensing of your prescription you may contact the Department of Consumer Protection, Drug Control Division, by calling (Department of Consumer Protection telephone number authorized pursuant to section 21a-2 of the general statutes)". The statement shall be printed in a size and style that allows such statement to be read without difficulty by consumers.

(d) The Commissioner of Consumer Protection shall adopt regulations, with the advice and assistance of the Commission of Pharmacy, in accordance with chapter 54 , concerning the implementation of a quality assurance program designed to detect, identify and prevent prescription errors in pharmacies. Such regulations shall require that each pharmacy implement a quality assurance program that describes in writing policies and procedures to be maintained in such pharmacy. Such policies and procedures shall include directions for communicating the details of a prescription error to the prescribing practitioner and to the patient, the patient's caregiver or appropriate family member if the patient is deceased or is unable to fully comprehend the communication. Such communication shall describe methods of correcting the prescription error or reducing the negative impact of the error on the patient. Such regulations shall require that records of all reported prescription errors shall be maintained in a manner ready for inspection for a minimum period of three years and that such records shall be made available for inspection by the Commissioner of Consumer Protection within forty-eight hours in any case where the commissioner is investigating a report of a prescription error.

(e) Records collected or maintained pursuant to this section shall not be required to be disclosed pursuant to subsection (a) of section 1-210 for a period of six months from the date such records were created pursuant to subsections (c) and (d) of this section and shall not be subject to subpoena or discovery or introduced into evidence in any judicial proceeding except as otherwise specifically provided by law.

Secs. 20-636 to 20-639. Reserved for future use.

CHAPTER 417

PURE FOOD AND DRUG ACT.

General Provisions

Sec. 21a-64. Distribution of drugs and poisons. Any person who, by himself, his servant or agent, distributes or gives away, in any street or highway or from house to house, any bottle, box, envelope or package containing any liquid medicine, or any pill, powder, tablet or other article, which contains any drug or poison, shall be fined not more than fifty dollars or imprisoned not more than one year or both.

Sec. 21a-65. Sale of hypodermic needles and syringes restricted. (a) A licensed manufacturer or licensed wholesaler may sell hypodermic needles and syringes only to the following: (1) To a licensed manufacturer, licensed wholesaler or licensed pharmacy; (2) to a physician, osteopath, dentist, veterinarian, embalmer, podiatrist or scientific investigator licensed to practice his profession in this state; (3) to a person in charge of a care-giving institution, as defined in subdivision (2) of section 20-571, incorporated college or scientific institution, but only for use by or in such care-giving institution, college or institution for medical or scientific purposes; (4) to a person in charge of a licensed or registered laboratory, but only for use in that laboratory for scientific and medical purposes; (5) to a farmer but only for use on his own animals or poultry; (6) to a business authorized in accordance with the regulations adopted under section 21a-66 to purchase hypodermic needles and syringes but only for legitimate industrial or medical use within that business; and (7) to a needle and syringe exchange program established pursuant to section 19a-124.

(b) Except as provided in subsection (a) of this section, no licensed manufacturer, licensed wholesaler or pharmacist shall sell and no person shall buy a hypodermic needle or syringe except upon a prescription of a prescribing practitioner, as defined in subdivision (22) of section 20-571, in a quantity greater than ten. Any such prescription shall be retained on file by the seller for a period of not less than three years and shall be accessible to any public officer engaged in the enforcement of this section. Such a prescription shall be valid for one year from the date thereof and purchases and sales may be made thereunder during such period, provided the seller shall confirm the continued need for such sales with the practitioner at least every six months if sales continue to be made thereunder. Hypodermic needles and syringes in a quantity of ten or less without a prescription may be provided or sold at retail only by the following: (1) By a pharmacy licensed in accordance with section 20-594, and in such pharmacy only by a licensed pharmacist or under his direct supervision; (2) by a needle exchange program established pursuant to section 19a-124; and (3) by a health care facility or a licensed health care practitioner for use by their own patients.

(c) At all locations where hypodermic needles and syringes are kept they shall be stored in a manner so as to be available only to authorized personnel and not be openly available to customers or patients. All used, disposable hypodermic needles and used, disposable syringes shall be destroyed. Destruction shall be conducted in a manner which renders such needles and syringes nonrecoverable. Used needles and syringes which have been discarded and are awaiting destruction shall be securely safeguarded or rendered nonreuseable.

(d) Any person who violates any provision of this section shall be fined not more than five hundred dollars or imprisoned not more than one year or both.

Sec. 21a-66. (Formerly Sec. 19-209b). Regulations re sale, purchase, handling and disposal of hypodermic needles and syringes. The commissioner of consumer protection shall adopt regulations in accordance with the provisions of chapter 54 to control the sale, purchase, handling and disposal of hypodermic needles and syringes pursuant to section 21a-65.

Sec. 21a-68. (Formerly Sec. 19-209d). Packaging of veterinary drugs. Any substance containing aspirin, or a controlled substance as defined in section 21a-240, or a legend drug as defined in section 20-l84a, sold or offered for sale in this state and intended to be administered to companion animals in the home shall be packaged in accordance with the requirements established by regulation under the Federal Poison Prevention Packaging Act of 1970, 84 Stat. 1670, 15 U.S.C. 1471, as amended.

Sec. 21a-69. (Formerly Sec. 19-209e). "Companion animal" defined by regulation. The commissioner of consumer protection, with the advice and assistance of the state board of veterinary registration and examination, shall by regulation adopted in accordance with chapter 54 define the term "companion animals" for the purposes of section 21a-68.

Sec. 21a-70. Registration of manufacturers and wholesalers of drugs. Sale of drugs limited.

(a) **Definitions.** As used in this section: (1) "Wholesaler" or "distributor" means a person whether within or without the boundaries of the state of Connecticut, who supplies drugs, medical devices or cosmetics prepared, produced or packaged by manufacturers, to other wholesalers, manufacturers, distributors, hospitals, prescribing practitioners, as defined in subdivision (22) of section 20-571, pharmacies, federal, state or municipal agencies, clinics or any other person as permitted under subsection (h) of this section, except that a retail pharmacy or a pharmacy within a licensed hospital which supplies to another such pharmacy a quantity of a non-controlled drug or a schedule III, IV or V controlled substance normally stocked by such pharmacies to provide for the immediate needs of a patient pursuant to a prescription or medication order of an authorized practitioner, a pharmacy within a hospital which supplies drugs to another hospital or an authorized practitioner for research purposes, and a retail pharmacy which supplies a limited quantity of a non-controlled drug or of a schedule II, III, IV or V controlled substance for emergency stock to a practitioner who is a medical director of a chronic and convalescent nursing home , of a rest home with nursing supervision or of a state correctional institution shall not be deemed a wholesaler under this section; (2) "manufacturer" means a person whether within or without the boundaries of the state of Connecticut who produces, prepares, cultivates, grows, propagates, compounds, converts or processes, directly or indirectly, by extraction from substances of natural origin or by means of chemical synthesis or by a combination of extraction and chemical synthesis, or who packages, replicates, labels or relabels a container under such manufacturer's own or any other trademark or label any drug, device or cosmetic for the purpose of selling such items. The words "drugs", "devices" and cosmetics shall have the meaning ascribed to them in section 21a-92; and (3) ""commissioner" means the Commissioner of Consumer Protection.

(b) **Registration of wholesalers and manufacturers of drugs required. Exception. Fees. Expenses.** No wholesaler or manufacturer shall operate as such until he has received a certificate of registration issued by the commissioner, which certificate shall be renewed annually, provided no such certificate shall be required of a manufacturer whose principal place of business is located outside the state, who is registered with the Federal Food and Drug Administration or any successor agency and who files a copy of such registration with the commissioner. A fee of one

hundred fifty dollars shall be charged for each wholesaler's certificate and renewal thereof and the fee for a manufacturers certificate and renewal thereof shall be two hundred twenty-five dollars for manufacturers employing not more than five licensed pharmacists or qualified chemists or both; three hundred dollars for manufacturers employing not more than ten licensed pharmacists or qualified chemists or both; and seven hundred fifty dollars for manufacturers employing more than ten licensed pharmacists or qualified chemists or both. No such certificate shall be issued to a manufacturer unless such drugs, medical devices or cosmetics are manufactured or compounded under the direct supervision of a licensed pharmacist or a qualified chemist. No certificate of registration shall be issued under this section until the applicant has furnished proof satisfactory to the commissioner that the applicant is equipped as to facilities and apparatus to properly carry on the business described in his application and that the applicant conforms to chapter 418 and regulation adopted thereunder.

(c) **The commissioner shall have the right to deny a certificate of registration** if he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the commissioner shall consider, at a minimum, the following factors:

(1) Any convictions or regulatory actions involving the applicant under any federal, state or local law relating to drug samples, wholesale or retail drug distribution, or distribution or possession of drugs including controlled substances;

(2) Any felony convictions of the applicant under federal, state or local laws;

(3) The applicant's past experience in the manufacture or distribution of drugs;

(4) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

(5) Suspension revocation or other sanction by federal, state or local government of any license or registration currently or previously held by the applicant for the manufacture or distribution of any drugs;

(6) Compliance with licensing or registration requirements under previously granted licenses or registrations;

(7) Compliance with requirements to maintain or make available to the commissioner or to federal, state or local law enforcement officials those records required by any federal or state statute or regulation;

(8) Failure to provide adequate control against the diversion, theft and loss of drugs;

(9) Provision of required security for legend drugs and, in the case of controlled substances, compliance with security requirements for wholesalers set forth in regulations adopted under chapter 420b; and

(10) Compliance with all regulations adopted to enforce the provisions of this section.

(d) **The commissioner may suspend, revoke or refuse to renew a registration,** or may issue a letter of reprimand or place a registrant on probationary status, for sufficient cause. Any of the following shall be sufficient cause for such action:

(1) The furnishing of false or fraudulent information in any application or other document filed with the commissioner;

(2) Any criminal conviction of the registrant under any federal or state statute concerning drugs;

(3) The suspension, revocation or other restriction or penalty issued against a license or registration related to drugs;

(4) Failure to provide adequate control against the diversion, theft and loss of drugs; or

(5) A violation of any provision of any federal or state statute or regulation concerning drugs.

(e) **Wholesalers shall operate in compliance with applicable federal, state and local statutes**, regulations and ordinances, including any applicable laws concerning controlled substances, drug product salvaging or reprocessing.

(f) **Wholesalers and manufacturers shall permit the commissioner, or his authorized representatives, to enter and inspect** their premises and delivery vehicles, and to audit their records and written operating procedures, at reasonable times and in a reasonable manner.

(g) **Before denying, suspending, revoking or refusing to renew a registration**, or before issuing a letter of reprimand or placing a registrant on probationary status, the commissioner shall afford the applicant or registrant an opportunity for a hearing in accordance with the provisions of chapter 54. Notice of such hearing may be given by certified mail. The commissioner may subpoena witnesses and require the production of records, papers and documents pertinent to such hearing.

(h) **Sale of drugs limited.** Regulations. No manufacturer or wholesaler shall sell any drugs except to the state or any political subdivision thereof, to another manufacturer or wholesaler, to any hospital recognized by the state as a general or specialty hospital, to any institution having a full-time pharmacist who is actively engaged in the practice of pharmacy in any such institution not less than thirty-five hours a week, to a chronic and convalescent nursing home having a pharmacist actively engaged in the practice of pharmacy based upon the ratio of one-tenth of one hour per patient per week but not less than twelve hours per week, to a practicing physician, podiatrist, dentist, optometrist or veterinarian or to a licensed pharmacy or a store to which a permit to sell nonlegend drugs has been issued as provided in section 43 of Public Act 95-264. The commissioner may adopt such regulations as are necessary to administer and enforce the provisions of this section.

(i) **Penalty.** Any person who violates any provision of this section shall be fined not more that five hundred dollars or imprisoned not more than six months or both.

Sec. 21a-70a. (Formerly Sec. 21a-250a). Distribution of noncontrolled drugs used as emergency stock. Noncontrolled drugs distributed as emergency stock to a medical director of a chronic and convalescent nursing home or a rest home with nursing supervision shall be supplied in containers which bear labels specifying the name of the drug and its strength, expiration date, lot number and manufacturer. Such noncontrolled drugs distributed as emergency stock shall be limited in type and quantity to those specifically documented and authorized by such medical director for use as emergency stock in such facility.

Sec 21a-70b The sale of certain products at flea markets restricted.

NEW) (a) As used in this section:

(1) "Flea Market" means any location other than a permanent retail store at which space is rented or otherwise made available to others for the conduct of business as transient or itinerant vendors, but does not include the location of (A) any sale by sample, catalogue or brochure for future delivery, or (B) any sale or sales presentation pursuant to a prior invitation issued by the owner or legal occupant of the premises; and

(2) "Manufacturer's or distributor's representative" means any person authorized by a manufacturer or distributor of any drug, as defined in section 21a-92 of the general statutes, to offer or sell any such product to the public at retail.

(b) No person, except a manufacturer's or distributor's representative, shall sell, offer for sale or knowingly permit the sale of any drug, as defined in section 21a-92 of the general statutes, at any flea market.

(c) Any manufacturer's or distributor's representative, when selling or offering for sale any drug, as defined in section 21a-92 of the general statutes, at any flea market shall carry on such representative's person written credentials indicating that such manufacturer's or distributor's representative is authorized by the manufacturer or distributor of such drugs to engage in the retail sale of such drug to the public. Such credentials shall be made available for inspection by any interested person upon the request of such person. Such credentials shall include the name of the manufacturer's or distributor's representative and may include the date, if any, on which such credentials expire.
(d) No person shall present credentials required under subsection (c) of this section that are false, misleading or fraudulently obtained.
(e) The Commissioner of Consumer Protection may adopt regulations, in accordance with the provisions of chapter 54 of the general statutes, to carry out the provisions of this section.

Sec. 21a-71. (Formerly Sec. 19-210a). Sale of food, drug or cosmetic at auction. No person shall sell any food, drug or cosmetic, as defined by section 21a-92, at an auction, unless such person has notified the commissioner of consumer protection, in writing, of such sale; provided this section shall not apply to the sale of food by any church, parent teacher association, charitable organization as defined by subdivision (1) of section 21a-176, or any organization of any political party. Such notice shall be given at least seven days prior to such sale and said commissioner may inspect such food, drug or cosmetic and prohibit the sale of the same if it is found to be unfit for human use. This section shall apply to the sale of unclaimed freight.

CHAPTER 418

UNIFORM FOOD, DRUG, & COSMETIC ACT

Sec. 21a-91. (Formerly Sec. 19-211). Short title and legislative intent. This chapter may be cited as the "Connecticut Food, Drug and Cosmetic Act," and is intended to enact state legislation: (1) Which will safeguard the public health and promote the public welfare by protecting the consuming public from injury by product use and the purchasing public from injury by merchandising deceit, arising from intrastate commerce in food, drugs, devices and cosmetics; (2) which shall be uniform, as provided in this chapter, with the Federal Food, Drug and Cosmetic Act and with the Federal Trade Commission Act, to the extent to which it outlaws the false advertisement of food, drugs, devices and cosmetics; and (3) which will promote uniformity of such legislation and its administration and enforcement in and throughout the United States.

Sec. 21a-92. (Formerly Sec. 19-212). Definitions. For the purposes of this chapter and section 21a-65, the following terms shall have the meanings hereinafter specified:

(1) "Advertisement" means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of food, drugs, devices or cosmetics;

(2) (A) "Color additive" means a material which (i) is a dye, pigment or other substance made by a process of synthesis or similar artifice, or extracted, isolated or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral or other source, and (ii) when added or applied to a food, drug or cosmetic, or to the human body or any of its parts, is capable, alone or through reaction with other substance, of imparting color thereto, except that the term "color additive" does not include any material exempted by regulation under the federal act, or which the commissioner, by regulation, determines is used, or intended to be used, solely for a purpose or purposes other than coloring; (B) the term "color" includes black, white and intermediate grays, as well as all other colors; (C) nothing in subparagraph (A) of this subdivision shall be construed to apply to any pesticide chemical, soil or plant nutrient, or other agricultural chemical used, or intended to be used, solely because of its effect in aiding, retarding or otherwise affecting, directly or indirectly, the growth or other natural physiological processes of produce of the soil which thereby affects its color, whether before or after harvest;

(3) "Commissioner" means the commissioner of consumer protection;

(4) "Contaminated with filth" applies to any food, drug, device or cosmetic not securely protected from dust or dirt, and as far as may be necessary, by all reasonable means, from all foreign or injurious contaminations;

(5) "Cosmetic" means (A) articles intended to be rubbed, poured, sprinkled or sprayed on, introduced into, or otherwise applied to the human body or any of its parts for cleansing, beautifying, promoting attractiveness or altering the appearance and (B) articles intended for use as a component of any such articles; except that such term shall not include soap;

(6) "Device", except when used in subdivision (15) of this section and in subsection (i) of section 21a-93, subsection (f) of section 21a-102, subsection (c) of section 21a-106 and subsection (c) of section 21a-112, means instruments, apparatus and contrivances, including their components, parts and accessories, intended (A) for use in the diagnosis, cure, mitigation, treatment

or prevention of disease in man or other animals or (B) to affect the structure or any function of the body of man or other animals;

(7) "Director" means the director of the agricultural experiment station;

(8) "Drug" means (A) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States or official National Formulary, or any supplement to any of them; (B) articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; (C) articles, other than food, intended to affect the structure or any function of the body of man or any other animal; and (D) articles intended for use as a component of any articles specified in this subdivision; but shall not include devices or their components, parts or accessories;

(9) "Federal act" means the Federal Food, Drug and Cosmetic Act, as amended, Title 21 U.S.C. 301 et seq.: 52 Stat. 1040 et seq.;

(10) "Food" means (A) articles used for food or drink for man or other animals, and (B) chewing gum, and (C) articles used for components of any such article;

(11) "Food additive" means any substance the intended use of which results or reasonably may be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food, including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting or holding food; and including any source of radiation intended for any such use, if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food, to be safe under the conditions of its intended use; except that such term does not include (A) a pesticide chemical in or on a raw agricultural commodity; or (B) a pesticide chemical to the extent that it is intended for use or is used in the production, storage or transportation of any raw agricultural commodity; or (C) a color additive; or (D) any substance used in accordance with a sanction or approval granted prior to June 12, 1963, or the Federal Food, Drug and Cosmetic Act, the Poultry Products Inspection Act (21 U.S.C. 451 et seq.) or the Meat Inspection Act of March 4, 1907, as amended;

(12) "Immediate container" shall not include package liners;

(13) "Intrastate commerce" means any and all commerce within the state of Connecticut and subject to its jurisdiction, and shall include the operation of any business or service establishment;

(14) "Label" means a display of written, printed or graphic matter upon the immediate container of any article, provided a requirement made by or under authority of this chapter that any information or other word or statement appear on the label shall not be considered to be complied with unless such information or other word or statement also appears on the outside container or wrapper, if any, of the retail package of such article, or is easily legible through the outside container or wrapper;

(15) "Labeling" means all labels and other written, printed or graphic matter (A) upon any article or any of its containers or wrappers, or (B) accompanying such article; provided, if an

article is alleged to be misbranded because the labeling is misleading, or if an advertisement is alleged to be false because it is misleading, then, in determining whether the labeling or advertisement is misleading, there shall be taken into account, among other things, not only representations made or suggested by statement, word, design, device or sound, or any combination thereof, but also the extent to which the labeling or advertisement fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertisement relates under the conditions of use prescribed in the labeling or advertisement thereof or under such conditions of use as are customary or usual, and provided the representation of a drug, in its labeling or advertisement, as an antiseptic shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment or dusting powder or for such other use as involves prolonged contact with the body;

(16) "Natural food" means food (A) which has not been treated with preservatives, antibiotics, synthetic additives, artificial flavoring or artificial coloring and (B) which has not been processed in a manner that makes such food significantly less nutritive. Processing of food by extracting, purifying, heating, fermenting, concentrating, dehydrating, cooling or freezing shall not, of itself, prevent the designation of such food as "natural food";

(17) "New drug" means (A) any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended or suggested in its labeling or (B) any drug the composition of which is such that such drug, as a result of investigation to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions, except that the provisions of this subsection pertaining to "effectiveness" shall not apply to any drug which (i) was commercially sold or used in the United States on October 9, 1962, (ii) was not a new drug as defined by this subsection prior to the enactment of these provisions, and (iii) was not covered by an effective application under section 21a-110 or under section 355 of the federal act, when such drug is intended solely for use under conditions prescribed, recommended, or suggested in labeling with respect to such drug on whichever of the above dates is applicable;

(18) "Official compendium" means the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, official National Formulary, or any supplement to any of them;

(19) "Organically grown food" means natural food which has not been subjected to pesticides, commercial fertilizers, as defined in subsection (a) of section 22-111b, or hormones;

(20) "Person" includes any individual, partnership, corporation or association;

(21) "Pesticide chemical" means any substance which, alone, in chemical combination or in formulation with one or more other substances is an "economic poison" within the meaning of the Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. 135-135k, and which is used in the production, storage or transportation of raw agricultural commodities;

(22) "Raw agricultural commodity" means any food in its raw or natural state, including all fruits that are washed, colored or otherwise treated in their unpeeled natural form prior to marketing;

(23) The term "safe" has reference to the health of man or animal;

(24) "Sale" means any and every sale and includes (A) manufacture, processing, packing, canning, bottling or any other production, preparation or putting up; (B) exposure, offer or any other proffer; (C) holding, storing or any other possessing; (D) dispensing, giving, delivering, serving or any other supplying; and (E) applying, administering or any other using.

Sec. 21a-93. (Formerly Sec. 19-213). Prohibited acts. The following acts and the causing thereof shall be prohibited: (a) The sale in intrastate commerce of any food, drug, device or cosmetic that is adulterated or misbranded; (b) the adulteration or misbranding of any food, drug, device or cosmetic in intrastate commerce; (c) the receipt in intrastate commerce of any food, drug, device or cosmetic that is adulterated or misbranded, and the sale thereof in such commerce for pay or otherwise; (d) the introduction or delivery for introduction into intrastate commerce of (1) any food in violation of section 21a-103 or (2) any new drug in violation of section 21a-110; (e) the dissemination within this state, in any manner or by any means or through any medium, of any false advertisement; (f) the refusal to permit (1) entry and the taking of a sample or specimen or the making of an investigation as authorized by section 21a-116, or (2) access to or copying of any record as authorized by section 21a-117; (g) the refusal to permit entry or inspection as authorized by section 21a-118; (h) the giving of a guaranty or undertaking in intrastate commerce, referred to in subsection (c) of section 21a-95, that is false; (i) the forging, counterfeiting, simulating or falsely representing, or, without proper authority, using, any mark, stamp, tag, label or other identification device authorized or required by regulations promulgated under the provisions of this chapter or of the federal act; (j) the alteration, mutilation, destruction, obliteration or removal of the whole or any part of the labeling of a food, drug, device or cosmetic, or the doing of any other act with respect to a food, drug, device or cosmetic, or the labeling or advertisement thereof, which results in a violation of this chapter; (k) the using in interstate commerce, in the labeling or advertisement of any drug, of any representation or suggestion that an application with respect to such drug is effective under section 355 of the federal act or under section 21a-110, or that such drug complies with the provisions of either such section; (l) the violation of any provision of section 21a-108; (m) in the case of a prescription drug distributed or offered for sale in this state, the failure of the manufacturer, packer or distributor thereof to maintain for transmittal, or to transmit, to any practitioner licensed by applicable state law to administer such drug who makes written request for information as to such drug, true and correct copies of all printed matter which is required to be included in any package in which that drug is distributed or sold, or such other printed matter as is approved by the commissioner or under the federal act. Nothing in this subsection shall be construed to exempt any person from any labeling requirement imposed by or under other provisions of this chapter unless specifically exempted under the federal act, as effective on April 26, 1974; (n) the using by any person to his own advantage, or revealing, other than to the commissioner or his duly authorized agents or to the courts when relevant in any judicial proceeding under this chapter, of any information acquired under authority of this chapter concerning any method, process, substance or any other subject which as a trade secret is entitled to protection; (o) (1) placing or causing to be placed upon any drug or device or upon the container of any drug or device, with intent to defraud, the trademark, trade name or other identifying mark, imprint or device of another or any likeness thereof; or (2) selling, dispensing, disposing of or causing to be sold, dispensed or disposed of or concealing or keeping in possession, control or custody, with intent to sell, dispense or dispose of, any drug, device or any container thereof transported, received or held for transportation in commerce, with knowledge that the trademark, trade name or other identifying mark, imprint or device of another or any likeness thereof has been placed thereon in a manner prohibited by subdivision (1) hereof;

or (3) making, selling, disposing of or causing to be made, sold or disposed of or keeping in possession, control or custody, or concealing, with intent to defraud, any punch, die, plate, stone or other thing designed to print, imprint or reproduce the trademark, trade name or other identifying mark, imprint or device of another or any likeness thereof upon any drug, device or container thereof.

Sec. 21a-94. (Formerly Sec. 19-214). Injunction proceedings. In addition to the remedies hereinafter provided, the commissioner is authorized to apply to the superior court for, and such court shall have jurisdiction upon hearing and for cause shown to grant, a temporary or permanent injunction restraining any person from violating any provision of section 21a-93, irrespective of whether or not there exists an adequate remedy at law.

Sec. 21a-95. (Formerly Sec. 19-215). Penalties. (a) Any person who violates any provision of section 21a-93 shall, on conviction thereof, be imprisoned not more than six months or fined not more than five hundred dollars or both; but, if the violation is committed after a conviction of such person under this subsection has become final, such person shall be imprisoned not more than one year or fined not more than one thousand dollars or both.

(b) Notwithstanding the provisions of subsection (a) of this section, any person who violates any provision of section 21a-93, with intent to defraud or mislead, shall be imprisoned not more than one year or fined not more than one thousand dollars or both.

(c) No person shall be subject to the penalties of subsection (a) of this section for having violated subsection (a) or (c) of section 21a-93 if he establishes a guaranty or undertaking signed by and containing the name and address of the person residing in this state from whom he received the article in good faith, to the effect that such article is not adulterated or misbranded within the meaning of this chapter. In such guaranty this chapter shall be designated by title.

(d) No publisher, radiobroadcast licensee, advertising agency or agency or medium for the dissemination of advertising, except the manufacturer, packer, distributor or seller of the article to which the advertisement relates, shall be subject to the penalties of subsection (a) of this section by reason of his dissemination of any false advertisement, unless he has refused, on the request of the commissioner, to furnish the name and address of the manufacturer, packer, distributor, seller or advertising agency in the United States, who caused him to disseminate such false advertisement.

Sec. 21a-96. (Formerly Sec. 19-216). Seizures. (a) Whenever the commissioner or his authorized agent finds, or has probable cause to believe, that any food, drug, device or cosmetic is offered or exposed for sale, or held in possession with intent to distribute or sell, or is intended for distribution or sale in violation of any provision of this chapter, whether it is in the custody of a common carrier or any other person, he may affix to such article a tag or other appropriate marking, giving notice that such article is, or is suspected of being, in violation of this chapter and has been embargoed. Within twenty-one days after an embargo has been placed upon any article, the embargo shall be removed by the commissioner or a summary proceeding for the confiscation of the article shall be instituted by the commissioner. No person shall remove or dispose of such embargoed article by sale or otherwise without the permission of the commissioner or his agent, or, after summary proceedings have been instituted, without permission from the court. If the embargo is removed by the commissioner or by the court, neither the commissioner nor the state shall be held liable for damages because of such embargo if the court finds that there was probable cause for the embargo.

(b) Proceedings before the superior court brought in accordance with this section shall be by complaint, verified by affidavit, which may be made on information and belief in the name of the commissioner against the article to be confiscated.

(c) The complaint shall contain: (1) A particular description of the article, (2) the name of the place where the article is located and (3) the name of the person in whose possession or custody the article was found, if such name is known to the person making the complaint or can be ascertained by reasonable effort, and (4) a statement as to the manner in which the article is adulterated or misbranded or the characteristics which render its distribution or sale illegal.

(d) Upon the filing of the verified complaint, the court shall issue a warrant directed to the proper officer to seize and take in his possession the article described in the complaint and bring the same before the court which issued the warrant and to summon the person named in the warrant, and any other person found in possession of the article, to appear at the time and place therein specified.

(e) Any such person shall be summoned by service of a copy of the warrant in the same manner as a summons issuing out of the court in which the warrant has been issued.

(f) The hearing upon the complaint shall be at the time and place specified in the warrant, which time shall not be less than five days or more than fifteen days from the date of issuing the warrant, but, if the execution and service of the warrant has been less than three days before the return of the warrant, either party shall be entitled to a reasonable continuance. Upon the hearing the complaint may be amended.

(g) Any person who appears and claims the food, drug, device or cosmetic seized under the warrant shall be required to file a claim in writing.

(h) If, upon the hearing, it appears that the article was offered or exposed for sale, or had in possession with intent to distribute or sell, or was intended for distribution or sale, in violation of any provision of this chapter, it shall be confiscated and disposed of by destruction or sale as the court may direct, but no such article shall be sold contrary to any provision of this chapter. The proceeds of any sale, less the legal costs and charges, shall be paid into the state treasury.

(i) If the article seized is not injurious to health and is of such character that, when properly packed, marked, branded or otherwise brought into compliance with the provisions of this chapter, its sale would not be prohibited, the court may order such article delivered to the owner upon the payment of the costs of the proceedings and the execution and delivery to the state department instituting the proceedings, as obligee, of a good and sufficient bond to the effect that such article will be brought into compliance with the provisions of this chapter under the supervision of said department, and the expenses of such supervision shall be paid by the owner obtaining release of the article under bond.

(j) Whenever the commissioner or any of his authorized agents finds in any room, building, vehicle of transportation, or other structure, any meat, seafood, poultry, vegetable, fruit or other perishable article which is unsound, or contains any filthy, decomposed or putrid substance, or that may be poisonous or deleterious to health or otherwise unsafe, the commissioner, or his authorized agent, shall forthwith condemn or destroy the same, or in any other manner render the same unsalable as a human food.

(k) The commissioner may, after notice and hearing, impose a civil penalty of not more than five hundred dollars for each separate offense on any person who removes any tag or other appropriate marking affixed to an article which has been embargoed or condemned in accordance with the provisions of this section, without the permission of the commissioner or his agent.

Sec. 21a-97. (Formerly Sec. 19-217). Prosecution for violation. Hearing before report of criminal violation. (a) Each state's attorney or assistant state's attorney of the superior court to whom the commissioner reports any violation of this chapter shall cause appropriate proceedings to be instituted without delay, and to be prosecuted as prescribed by law.

(b) Before any violation of this chapter, except for any violation of subdivision (l) of section 21a-93, is reported by the commissioner to any such attorney for the institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given

appropriate notice and an opportunity to present his views to the commissioner, either orally or in writing, with regard to such contemplated proceeding.

Sec. 21a-98. (Formerly Sec. 19-218). Report of minor violations not required. Nothing in this chapter shall be construed as requiring the commissioner to report, for the institution of proceedings under this chapter, minor violations of this chapter, whenever he believes that the public interest will be adequately served in the circumstances by a suitable written notice or warning.

Sec. 21a-99. (Formerly Sec. 19-219). Proceedings in name of state. All such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the state of Connecticut.

Sec. 21a-105. (Formerly Sec. 19-225). Adulterated drugs and devices. A drug or device shall be deemed to be adulterated: (a) (1) If it consists, in whole or in part, of any filthy, putrid or decomposed substance; or (2) if it has been produced, prepared, packed or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (3) if it is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (4) if it is a drug and it bears or contains, for the purposes of coloring only, a color additive which is unsafe within the meaning of section 21a-104; or (5) if it is a drug which has been stored, kept or held under conditions contrary to the cautionary label statements on the package or contrary to the recommendations as stated within the official compendium; or (6) if it has not been manufactured in accordance with good manufacturing practices as defined in the Federal Food and Drug Act Parts 211 and 820; (b) if it purports to be, or is represented as, a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium; such determination as to strength, quality or purity to be made in accordance with the tests or methods of assay set forth in such compendium or prescribed by regulations promulgated under Section 351(b) of the federal act, provided no drug defined in an official compendium shall be deemed to be adulterated under this subsection because it differs from the standard of strength, quality or purity therefor set forth in such compendium, if its difference in strength, quality or purity from such standard is plainly stated on its label and provided, whenever a drug is recognized in both the United States Pharmacopoeia and the Homeopathic Pharmacopoeia of the United States, it shall be subject to the requirements of the United States Pharmacopoeia unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia; (c) if it is not subject to the provisions of subsection (b) of this section and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess; (d) if it is a drug and any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part therefor.

Sec. 21a-106. (Formerly Sec. 19-226). Misbranded drugs and devices. A drug or device shall be deemed to be misbranded:

(a) If its labeling is false or misleading in any particular. Any statement on the label or labeling either directly or indirectly implying that the product is recommended or endorsed by any agency of the federal or state government shall be considered misleading, unless the agency concerned has approved the statement prior to its use, or unless such statement is authorized by Section 357(c) of the federal act;

(b) If in package form, unless it bears a label containing (1) the name and place of business of the manufacturer, packer or distributor, except that the label of a prescription drug packaged after October 1, 1976, shall contain the name and place of business of the manufacturer of the final dosage form of the drug and, if different, the name and place of business of the packer or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure or numerical count, provided reasonable variations shall be permitted and exemptions as to small packages shall be established by regulations promulgated by the commissioner and director, acting jointly, or by regulations issued under the federal act;

(c) If any information or other word or statement, required by or under authority of this chapter to appear on the label or labeling, is not prominently placed thereon with such conspicuousness, as compared with other words, statements, designs or devices in the labeling, and in such terms, as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(d) If it is for use by man and contains any quantity of the narcotic or hypnotic substance alpha-eucaine, beta-eucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marihuana, morphine, opium, paraldehyde, peyote or sulphonmethane, or any chemical derivative of any such substance, which derivative has been designated as habit-forming by regulations promulgated under Section 352(d) of the federal act; unless its label bears the name and quantity or proportion of such substance or derivative and in juxtaposition therewith the statement "Warning--may be habit-forming";

(e) (1) If it is a drug, unless (A) its label bears, to the exclusion of any other nonproprietary name, except the applicable systematic chemical name or the chemical formula, (i) the established name, as defined in subdivision (2) of this subsection, of the drug, if such there be, and (ii), in case it is fabricated from two or more ingredients, the established name and quantity of each active ingredient, including the kind and quantity or proportion of any alcohol, and also including, whether active or not, the established name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetophenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein: Provided the requirement for stating the quantity of the active ingredients, other than those specifically named in this paragraph, shall apply only to prescription drugs packaged prior to July 1, 1980, and provided further, the requirement for stating the quantity or proportion of the active ingredients, other than those specifically named in this paragraph, shall apply to all drugs packaged on or after July 1, 1980, except nonprescription drugs which are also cosmetics; and (B) if it is a prescription drug, unless the established name of such drug or ingredient, as the case may be, on such label (and on any labeling on which a name for such drug or ingredient is used) is printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient. To the extent that compliance with the requirements of clause (A) (ii) or clause (B) is impracticable, exemptions shall be established by regulations promulgated by he commissioner and director, acting jointly, or by regulations issued under the federal act. (2) As used in this subsection (e), the term, "established name," with respect to a drug or ingredient thereof, means (A) the applicable official name designated pursuant to Section 358 of the federal act, or (B), if there is no such name and such drug, or such ingredient, is an article recognized in an official compendium, then the official title thereof in such compendium, or (C) if neither clause (A) nor clause (B) applies, then the common or usual name, if any, of such ingredient. Where clause (B) applies to an article recognized in the United States Pharmacopoeia and in the Homeopathic Pharmacopoeia under different official titles, the official title used in the United States Pharmacopoeia shall apply unless it is labeled and offered for sale as a homeopathic drug, in which case the official title used in the Homeopathic Pharmacopoeia shall apply;

(f) Unless its labeling bears (1) adequate directions for use and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users; provided, when any requirement of subdivision (1) of this subsection, as applied to any drug or device, is not necessary for the protection of the public health, the commissioner and director, acting jointly, shall promulgate regulations exempting such drug or device from such requirement; provided further, articles exempted under regulations issued under Section 352(f) of the federal act shall also be exempt from the requirements of this subsection;

(g) If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein; provided the method of packing may be modified with the consent of the commissioner and director, acting jointly, and provided whenever a drug is recognized in both the United States Pharmacopoeia and the Homeopathic Pharmacopoeia of the United States, it shall be subject to the requirements of the United States Pharmacopoeia with respect to packaging and labeling unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopoeia of the United States, and not to those of the United States Pharmacopoeia; provided further, in the event of inconsistency between the requirements of this subsection and those of subsection (e) as to the name by which the drug or its ingredients shall be designated, the requirements of subsection (e) shall prevail;

(h) If it has been found by the commissioner to be a drug liable to deterioration, unless it is packaged in such form and manner, and its label bears a statement of such precautions, as the commissioner and director, acting jointly, by regulations, require as necessary for the protection of public health; provided no such regulations shall be established for any drug recognized in an official compendium until the commissioner has informed the appropriate body charged with the revision of such compendium of the need for such packaging or labeling requirements and such body has failed within a reasonable time to prescribe such requirements;

(i) (1) If it is a drug and its container is so made, formed or filled as to be misleading or (2) if it is an imitation of another drug or (3) if it is offered for sale under the name of another drug;

(j) If it is dangerous to health when used in the dosage, or with the frequency or duration, prescribed, recommended or suggested in the labeling thereof;

(k) If it is a legend drug, as defined in subdivision (14) of section 20-571, that is not administered, dispensed, prescribed or otherwise possessed or distributed in accordance with federal and state laws and regulations.

(l) If it is a color additive, the intended use of which in or on drugs is for the purpose of coloring only, unless its packaging and labeling are in conformity with such packaging and labeling requirements contained in regulations issued under the federal act;

(m) In the case of any prescription drug distributed or offered for sale in any state, unless the manufacturer, packer or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer or distributor with respect to that drug a true statement of (1) the established name, as defined in subsection (e) (2) of this section, printed prominently and in type at least half as large as that used for any trade or brand name thereof, (2) the formula showing quantitatively each ingredient of such drug to the extent required for labels under subsection (e) of this section, and (3) such other information in brief summary relating to side effects, contraindications and effectiveness as required in regulations issued under the federal act unless it is a drug which has been exempted from the labeling provisions of the federal act, as effective on April 26, 1974, or is permitted to be sold without a prescription under the federal act, as effective on said date;

(n) If it is a drug and was manufactured, prepared, propagated, compounded or processed in an establishment in this state not duly registered under section 21a-70;

(o) If it is, or purports to be, or is represented as a drug composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin or any other antibiotic drug, or any derivative thereof, unless (1) it is from a batch with respect to which a certificate or release has been issued pursuant to Section 357 of the federal act, and (2) such certificate or release is in effect with respect to such drug; provided that this subsection shall not apply to any drug or class of drugs exempted by regulations promulgated under Section 357 (c) or (d) of the federal act. For the purpose of this subsection, "antibiotic drug" means any drug intended for use by man containing any quantity of any chemical substance which is produced by a microorganism and which has the capacity to inhibit or destroy microorganisms in dilute solution, and the chemically synthesized equivalent of any such substance.

Sec. 21a-107. (Formerly Sec. 19-226a). Repackaged drugs not considered misbranded, when. Notwithstanding the provisions of section 21a-106, as amended by section 55 of Public Act 95-264, concerning misbranding of drug or devices, a drug shall not be considered misbranded when repackaged by a pharmacy or an institutional pharmacy into stock packages for use within the pharmacy or the institutional pharmacy, provided the stock packages contain a label indicating the drug's name, strength, lot number, manufacturer and expiration date, if any.

Sec. 21a-108. (Formerly Sec. 19-227). Illegal obtaining or supplying of drugs. Forged labels. (1) No person shall obtain or attempt to obtain a drug covered by subsection (k) of section 21a-106 or procure or attempt to procure the administration of such drug: (a) By fraud, deceit, misrepresentation or subterfuge; or (b) by the forgery or alteration of a prescription or of any written order; or (c) by the concealment of a material fact; or (d) by the use of a false statement in any prescription, order or report required by this chapter.

(2) No person shall manufacture, possess, have under his control, sell, prescribe, administer, dispense or compound any drug covered by said subsection, except as authorized in this chapter.

(3) No person shall, for the purpose of obtaining a drug covered by said subsection, falsely assume the title of, or represent himself to be, a manufacturer, wholesaler, apothecary, physician, dentist, veterinarian or other authorized person.

(4) No person shall make or utter any false or forged prescription or false or forged written order.

(5) No person shall affix any false or forged label to a package or receptacle containing any drug covered by said subsection.

Sec. 21a-109. (Formerly Sec. 19-228). Drugs dispensed on prescription. A drug dispensed on a written or oral prescription of a practitioner licensed by law to administer such drug, except a drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail, shall, if such drug bears a label containing the name and place of business of the dispenser, the serial number and date of filling or refilling of such prescription, the name of such practitioner licensed by law to administer such drugs and the name of the patient, be exempt from the requirements of section 21a-106, except that no prescription for a legend drug or any derivative of any legend drug, shall be refilled except upon the order of the practitioner licensed by law to administer such drug.

Sec. 21a-110. (Formerly Sec. 19-229). New drugs. (a) No person shall sell, deliver, offer for sale, hold for sale or give away any new drug unless (1) an application with respect thereto has been approved under Section 355 of the federal act or (2), when not subject to the federal act, unless such drug has been tested and has been found to be safe for use and effective in use under the conditions prescribed, recommended or suggested in the labeling thereof, and prior

to selling or offering for sale such drug, there has been filed with the commissioner an application setting forth (A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (B) a full list of the articles used as components of such drug; (C) a full statement of the composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing and packing of such drug; (E) such samples of such drug and of the articles used as components thereof as the commissioner may require; and (F) specimens of the labeling proposed to be used for such drug.

(b) An application provided for in subdivision (2) of subsection (a) shall become effective on the one hundred eightieth day after the filing thereof, except that, if the commissioner finds, after due notice to the applicant and giving him an opportunity for a hearing, that the drug is not safe or not effective for use under the conditions prescribed, recommended or suggested in the proposed labeling thereof, he shall, prior to the effective date of the application, issue an order refusing to permit the application to become effective.

(c) This section shall not apply: (1) To a drug intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs, provided the drug shall be plainly labeled in compliance with regulations issued under Section 355 (i) or 357 (d) of the federal act; or (2) to a drug sold in this state at any time prior to the enactment of this chapter or introduced into interstate commerce at any time prior to the enactment of the federal act; or (3) to any drug which is licensed under Title 42, U.S.C. 262; or (4) to any drug subject to subsection (o) of section 21a-106.

(d) An order refusing to permit an application under this section to become effective may be revoked by the commissioner.

Sec. 21a-111. (Formerly Sec. 19-230). Adulterated cosmetics. A cosmetic shall be deemed to be adulterated: (a) If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual; provided this provision shall not apply to coal-tar hair dye, the label of which bears the following legend conspicuously displayed thereon: "Caution--This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness," and the labeling of which bears adequate directions for such preliminary testing, and provided, for the purposes of this subsection and subsection (e), the term "hair-dye" shall not include eyelash dyes or eyebrow dyes; (b) if it consists in whole or in part of any filthy, putrid or decomposed substance; (c) if it has been produced, prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth or whereby it may have been rendered injurious to health; (d) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (e) if it is not a hair-dye and it bears or contains a color additive which is unsafe within the meaning of section 21a-104.

Sec. 21a-112. (Formerly Sec. 19-231). Misbranded cosmetics. A cosmetic shall be deemed to be misbranded: (a) If its labeling is false or misleading in any particular. Any statement on the label or labeling of such cosmetic, either directly or indirectly implying that the product is recommended or endorsed by any agency of the federal or state government, shall be considered misleading, unless such agency has approved such statement prior to such use;

(b) if in package form, unless it bears a label containing (1) the name and place of business of the manufacturer, packer or distributor and (2) an accurate statement of the quantity of the contents in terms of weight, measure or numerical count, provided, under subdivision (2) of this

subsection, reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the commissioner and director, acting jointly;

(c) if any information or other word or statement, required by or under authority of this chapter to appear on the label or labeling, is not prominently placed thereon with such conspicuousness, as compared with other words, statements, designs or devices in the labeling, and in such terms, as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use; or (d) if its container is so made, formed or filled as to be misleading.

Sec. 21a-113. (Formerly Sec. 19-232). False advertisement of food, drugs, devices and cosmetics. An advertisement of a food, drug, device or cosmetic shall be deemed to be false, if it is false or misleading in any particular. Any statement either directly or indirectly implying that the product is recommended or endorsed by any agency of the federal or state government shall be considered misleading, unless the agency concerned has approved the statement prior to its use.

Sec. 21a-114. (Formerly Sec. 19-233). When advertisement of drugs and devices deemed to be false. The advertisement of a drug or device representing it to have any effect in albuminuria, appendicitis, arteriosclerosis, blood poison, bone disease, Bright's disease, cancer, carbuncles, cholecystitis, diabetes, diphtheria, dropsy, erysipelas, gallstones, heart and vascular diseases, high blood pressure, mastoiditis, measles, meningitis, mumps, nephritis, otitis media, paralysis, pneumonia, poliomyelitis (infantile paralysis), prostate gland disorders, pyelitis, scarlet fever, sexual impotence, sinus infection, smallpox, tuberculosis, tumors, typhoid, uremia or venereal disease, shall also be deemed to be false; except that no advertisement not in violation of section 21a-113 shall be deemed to be false under this section if it is disseminated only to members of the medical, dental or veterinary profession, or appears only in the scientific periodicals of these professions, or is disseminated only for the purpose of public health education by persons not commercially interested, directly or indirectly, in the sale of such drugs or devices; provided, whenever the commissioner and director, acting jointly, agree that an advance in medical science has made any type of self-medication safe as to any of the diseases named above, the commissioner and director, acting jointly, shall, by regulation, authorize the advertisement of drugs having curative or therapeutic effect for such disease, subject to such conditions and restrictions as the commissioner and director, acting jointly, deem necessary in the interests of public health; and provided this section shall not be construed as indicating that self-medication for diseases other than those named herein is safe or efficacious.

Sec. 21a-115. (Formerly Sec. 19-234). Regulations and hearings. (a) The authority to promulgate regulations for the efficient enforcement of this chapter is vested in the commissioner and director, acting jointly.

(b) The purpose of this chapter being to promote uniformity of state legislation with the federal act, the commissioner and director, acting jointly, are authorized (1) to adopt, so far as applicable, the regulations from time to time promulgated under the federal act, (2) to make the regulations promulgated under this chapter conform, so far as practicable, with those promulgated under the federal act and (3) to adopt regulations banning the sale or introduction into intrastate commerce of any adulterated food, drug, device or cosmetic, which adversely affects the health or safety of the public.

(c) Hearings authorized or required by this chapter shall be conducted by the commissioner and director, acting jointly, or their authorized representative designated for the purpose.

(d) The commissioner and director, acting jointly, shall hold a public hearing upon a proposal to promulgate any new or amended regulation under this chapter, which requires or

prohibits any practice in intrastate commerce; except in the case of a proposal to adopt an applicable regulation promulgated under the federal act. The commissioner shall give appropriate notice of such hearing. The notice shall state the time and place of the hearing to be held not fewer than ten days after the date of such notice, except in the case of an emergency found by the commissioner. No regulation promulgated under this chapter, by order issued after such hearing, shall take effect prior to the thirtieth day after the date of such order, except in the case of an emergency found by the commissioner.

(e) In the promulgation of regulations under the provisions of this section applicable to prescribing practitioners, care-giving institutions, and correctional and juvenile training institutions, as defined in subdivision (6) of section 201-184a, as amended by section 2 of Public Act 95-264, the commissioner of consumer protection shall act in place of the director. Existing regulations shall continue in effect unless superseded by action of said commissioner pursuant to this subsection.

Sec. 21a-116. (Formerly Sec. 19-235). Examinations and investigations. (a) The commissioner shall cause the investigation and examination of food, drugs, devices and cosmetics subject to this chapter. The commissioner or his authorized representative shall have the right (1) to take a sample or specimen of any such article, for examination under this chapter, upon tendering the market price therefor to the person having such article in custody and (2) to enter any place or establishment within this state, at reasonable times, for the purpose of taking a sample or specimen of such article, for such examination. (3) Samples or specimens taken under the provisions of subsection (a) of this section shall be submitted to the agricultural experiment station or to the laboratory services section of the department of health services for examination.

(b) When a sample or specimen of any such article is taken for examination under this chapter, the commissioner shall, upon request, provide a part thereof for examination by any person named on the label of such article or the owner thereof, or his attorney or agent; except that the commissioner is authorized, by regulations, to make such reasonable exceptions from, and to impose such reasonable terms and conditions relating to, the operation of this subsection as he finds necessary for the proper administration of the provisions of this chapter.

(c) For the purpose of enforcing the provisions of this chapter, pertinent records of any administrative agency of the state government shall be open to inspection by the commissioner or his authorized representative.

Sec. 21a-117. (Formerly Sec. 19-236). Records of intrastate shipment. For the purpose of enforcing the provisions of this chapter, carriers engaged in intrastate commerce, and persons receiving food, drugs, devices or cosmetics in intrastate commerce or holding such articles so received, shall, upon the request of an authorized representative of the commissioner, permit such representative, at reasonable times, to have access to and to copy all records showing the movement in intrastate commerce of any food, drug, device or cosmetic, or the holding thereof during or after such movement, and the quantity, shipper and consignee thereof; and no such carrier or person shall fail to permit such access to, and the copying of, any such records so requested when such request is accompanied by a statement in writing specifying the nature or kind of food, drug, device or cosmetic to which such request relates; provided evidence obtained under this section shall not be used in a criminal prosecution of the person from whom obtained and provided carriers shall not be subject to the other provisions of this chapter by reason of their receipt, carriage, holding or delivery of food, drugs, devices or cosmetics in the usual course of business as carriers.

Sec. 21a-118. (Formerly Sec. 19-237). Inspections. Right to hearing. Reinspection of food facilities; costs imposed. Suspension or revocation of license for violation of provisions

of chapter 417. (a) For the purpose of enforcing the provisions of chapter 417 and this chapter, the commissioner, or his authorized representative, is authorized (1) to enter, at reasonable times, any factory, warehouse or establishment subject to this chapter, or to enter any vehicle being used to transport or hold food, drugs, devices or cosmetics in intrastate commerce and (2) to inspect, at reasonable times, such factory, warehouse, establishment or vehicle and all pertinent equipment, finished and unfinished materials, containers, labeling and advertisements, records, files and papers therein.

(b) If an inspection reveals a violation of any provision of this chapter concerning a food factory, food warehouse or food establishment, the commissioner shall notify the owner of such factory, warehouse or establishment of any such violation and his right to a hearing under this section by certified mail within fifteen days of the date of such original inspection. Such owner may contest the violations cited in such notice by requesting a hearing in writing by certified mail within fifteen days of the date of receipt of such notice. The commissioner shall grant such a request and conduct a hearing in accordance with the provisions of chapter 54. The cost of all reinspections necessary to determine compliance with any such provision shall be assumed by such owner at an amount determined by the commissioner, except that if the first reinspection following the original inspection indicates compliance with such provision no charge shall be made.

(c) If an inspection reveals a violation of any provision of chapter 417 or this chapter concerning any drug or device by any establishment licensed in accordance with the provisions of chapter 417, the commissioner may suspend or revoke the license of such establishment after notice and a hearing conducted in accordance with the provisions of chapter 54.

Sec. 21a-119. (Formerly Sec. 19-238). Publicity. (a) The commissioner may cause to be published, from time to time, reports summarizing all judgments, decrees and court orders which have been rendered under this chapter, including the nature of the charge and the disposition thereof.

(b) The commissioner may also cause to be disseminated such information regarding food, drugs, devices or cosmetics as the commissioner deems necessary in the interest of public health and the protection of the consumer against fraud. Nothing in this section shall be construed to prohibit the commissioner and director from collecting, reporting and illustrating the results of their examinations and investigations under this chapter.

Sec. 21a-120. (Formerly Sec. 19-239). Interpretation. This chapter and the regulations promulgated hereunder shall be so interpreted and construed as to effectuate its general purpose to enact state legislation uniform with the federal act.

CHAPTER 420b
DEPENDENCY PRODUCING DRUGS ACT
Part I- General Provisions

Sec. 21a-240. (Formerly Sec. 19-443). Definitions. The following words and phrases, as used in this chapter, shall have the following meanings, unless the context otherwise requires:

(1) "Abuse of drugs" means the use of controlled substances solely for their stimulant, depressant or hallucinogenic effect upon the higher functions of the central nervous system and not as a therapeutic agent prescribed in the course of medical treatment or in a program of research operated under the direction of a physician or pharmacologist;

(2) "Administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion or any other means, to the body of a patient or research subject by: (A) A practitioner, or, in his presence, by his authorized agent, or (B) the patient or research subject at the direction and in the presence of the practitioner, or (C) a nurse or intern under the direction and supervision of a practitioner;

(3) "Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor or dispenser. It does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman;

(4) "Amphetamine-type substances" include amphetamine, optical isomers thereof, salts of amphetamine and its isomers, and chemical compounds which are similar thereto in chemical structure or which are similar thereto in physiological effect, and which show a like potential for abuse, which are controlled substances under this chapter unless modified;

(5) "Barbiturate-type drugs" include barbituric acid and its salts, derivatives thereof and chemical compounds which are similar thereto in chemical structure or which are similar thereto in physiological effect, and which show a like potential for abuse, which are controlled substances under this chapter unless modified;

(6) "Bureau" means the Bureau of Narcotics and Dangerous Drugs, United States Department of Justice, or its successor agency;

(7) "Cannabis-type substances" include all parts of any plant, or species of the genus cannabis or any infra specific taxon thereof whether growing or not; the seeds thereof; the resin extracted from any part of such a plant; and every compound, manufacture, salt, derivative, mixture or preparation of such plant, its seeds or resin; but shall not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture or preparation of such mature stalks, except the resin extracted therefrom, fiber, oil or cake, or the sterilized seed of such plant which is incapable of germination. Included are cannabinon, cannabinol, cannabidiol and chemical compounds which are similar to cannabinon, cannabinol or cannabidiol in chemical structure or which are similar thereto in physiological effect, and which show a like potential for abuse, which are controlled substances under this chapter unless modified;

(8) "Controlled drugs" are those drugs which contain any quantity of a substance which has been designated as subject to the Federal Controlled Substances Act, or which has been designated as a depressant or stimulant drug pursuant to federal food and drug laws, or which has been designated by the commissioner of consumer protection pursuant to section 21a-243, as having a stimulant, depressant or hallucinogenic effect upon the higher functions of the central nervous system and as having a tendency to promote abuse or psychological or physiological dependence, or both. Such controlled drugs are classifiable as amphetamine-type, barbiturate-type, cannabis-type, cocaine- type, hallucinogenic, morphine-type and other stimulant and depressant drugs. Specifically excluded from controlled drugs and controlled substances are alcohol, nicotine and caffeine;

(9) "Controlled substance" means a drug, substance, or immediate precursor in schedules I to V, inclusive, of the Connecticut controlled substance scheduling regulations adopted pursuant to section 21a-243;

(10) "Counterfeit substance" means a controlled substance which, or the container or labeling of which, without authorization, bears the trademark, trade name or other identifying mark, imprint, number or device, or any likeness thereof, of a manufacturer, distributor or dispenser other than the person who in fact manufactured, distributed or dispensed the substance;

(11) "Deliver or delivery" means the actual, constructive or attempted transfer from one person to another of a controlled substance, whether or not there is an agency relationship;

(12) "Dentist" means a person authorized by law to practice dentistry in this state;

(13) "Dispense" means to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling or compounding necessary to prepare the substance for the delivery;

(14) "Dispenser" means a practitioner who dispenses;

(15) "Distribute" means to deliver other than by administering or dispensing a controlled substance;

(16) "Distributor" means a person who distributes and includes a wholesaler who is a person supplying or distributing controlled drugs which he himself has not produced or prepared to hospitals, clinics, practitioners, pharmacies, other wholesalers, manufacturers and federal, state and municipal agencies;

(17) "Drug" means (A) substances recognized as drugs in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; (B) substances intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or animals; (C) substances, other than food, intended to affect the structure or any function of the body of man or animals; and (D) substances intended for use as a component of any article specified in subparagraph (A), (B) or (C) of this subdivision. It does not include devices or their components, parts or accessories;

(18) "Drug dependence"means a psychoactive substance dependence on drugs as that condition is defined in the most recent edition of the "Diagnostic and statistical manual of mental disorders" of the American Psychiatric Association.

(19) "Drug-dependent person"means a person who has a psychoactive substance dependence on drugs as that condition is defined in the "Diagnostic and statistical manual of mental disorders" of the American Psychiatric Association.

(20) (A) "Drug paraphernalia" refers to equipment, products and materials of any kind which are used, intended for use or designed for use in planting, propagating, cultivating, growing, harvesting, manufacturing, compounding, converting, producing, processing, preparing, testing, analyzing, packaging, repackaging, storing, containing or concealing, or injecting, ingesting, inhaling or otherwise introducing into the human body, any controlled substance contrary to the provisions of this chapter including, but not limited to: (i) Kits intended for use or designed for use in planting, propagating, cultivating, growing or harvesting of any species of plant which is a controlled substance or from which a controlled substance can be derived; (ii) kits used, intended for use or designed for use in manufacturing, compounding, converting, producing, processing or preparing controlled substances; (iii) isomerization devices used, intended for use in increasing the potency of any species of plant which is a controlled substance; (iv) testing equipment used, intended for use or designed for use in identifying or analyzing the strength, effectiveness or purity of controlled substances; (v) dilutents and adulterants, such as quinine hydrochloride, mannitol, mannite, dextrose and lactose used, intended for use or designed for use in cutting controlled substances; (vi) separation gins and sifters used, intended for use or designed for use in removing twigs and seeds from, or in otherwise cleaning or refining, marihuana; (vii) capsules and other containers used, intended for use or designed for use in packaging small quantities of controlled

substances; (viii) containers and other objects used, intended for use or designed for use in storing or concealing controlled substances; (ix) in a quantity greater that thirty hypodermic syringes, needles and other objects used, intended for use or designed for use in parenterally injecting controlled substances into the human body; (x) objects used, intended for use or designed for use in ingesting, inhaling, or otherwise introducing marihuana, cocaine, hashish, or hashish oil into the human body, such as: Metal, wooden, acrylic, glass, stone, plastic or ceramic pipes with screens, permanent screens, hashish heads or punctured metal bowls; water pipes; carburetion tubes and devices; smoking and carburetion masks; roach clips: Meaning objects used to hold burning material, such as a marihuana cigarette, that has become too small or too short to be held in the hand; miniature cocaine spoons, and cocaine vials; chamber pipes; carburetor pipes; electric pipes; airdriven pipes; chillums; bongs or ice pipes or chillers;

(B) "Factory" means any place used for the manufacturing, mixing, compounding, refining, processing, packaging, distributing, storing, keeping, holding, administering or assembling illegal substances contrary to the provisions of this chapter, or any building, rooms or location which contains equipment or paraphernalia used for this purpose;

(21) "Federal Controlled Substances Act, 21 USC 801 et seq." means Public Law 91-513, the Comprehensive Drug Abuse Prevention and Control Act of 1970;

(22) "Federal food and drug laws" means the Federal Food, Drug and Cosmetic Act, as amended, Title 21 USC 301 et seq.;

(23) "Hallucinogenic substances" are psychodysleptic substances which assert a confusional or disorganizing effect upon mental processes or behavior and mimic acute psychotic disturbances. Exemplary of such drugs are mescaline, peyote, psilocyn and d-lysergic acid diethylamide, which are controlled substances under this chapter unless modified;

(24) "Hospital" as used in sections 21a-243 to 21a-285, inclusive, means an institution for the care and treatment of the sick and injured, approved by the department of health services or state department of mental health as proper to be entrusted with the custody of controlled drugs and substances and professional use of controlled drugs and substances under the direction of a licensed practitioner;

(25) "Intern" means a person who holds a degree of doctor of medicine or doctor of dental surgery or medicine and whose period of service has been recorded with the department of health services and who has been accepted and is participating in training by a hospital or institution in this state. Doctors meeting the foregoing requirements and commonly designated as "residents" and "fellows" shall be regarded as interns for purposes of this chapter;

(26) "Immediate precursor" means a substance which the commissioner of consumer protection has found to be, and by regulation designates as being, the principal compound commonly used or produced primarily for use, and which is an immediate chemical intermediary used or likely to be used, in the manufacture of a controlled substance, the control of which is necessary to prevent, curtail or limit manufacture;

(27) "Laboratory" means a laboratory approved by the state department of consumer protection as proper to be entrusted with the custody of controlled substances and the use of controlled substances for scientific and medical purposes and for purposes of instruction, research or analysis;

(28) "Manufacture" means the production, preparation, cultivation, growing, propagation, compounding, conversion or processing of a controlled substance, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container, except that this term does not include the preparation or compounding of a controlled substance by an individual for his own use or the preparation, compounding, packaging or labeling of a controlled substance:

(A) By a practitioner as an incident to his administering or dispensing of a controlled substance in the course of his professional practice, or (B) by a practitioner, or by his authorized agent under his supervision, for the purpose of, or as an incident to, research, teaching or chemical analysis and not for sale;

(29) "Marihuana" means all parts of any plant, or species of the genus cannabis or any infra specific taxon thereof, whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. It does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture or preparation of such mature stalks, except the resin extracted therefrom, fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination. Included are cannabinon, cannabinol or cannabidiol and chemical compounds which are similar to cannabinon, cannabinol or cannabidiol in chemical structure or which are similar thereto in physiological effect, and which show a like potential for abuse, which are controlled substances under this chapter unless modified;

(30) "Narcotic substance" means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis: (A) Morphine type: (i) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate which are similar thereto in chemical structure or which are similar thereto in physiological effect and which show a like potential for abuse, which are controlled substances under this chapter unless modified; (ii) any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause (i), but not including the isoquinoline alkaloids of opium; (iii) opium poppy and poppy straw; (B) cocaine type, coca leaves and any salt, compound, derivative or preparation of coca leaves, and any salt, compound, isomer, derivatives or preparation thereof which is chemically equivalent or identical with any of these substances or which are similar thereto in physiological effect and which show a like potential for abuse, but not including decocainized coca leaves or extractions of coca leaves which do not contain cocaine or ecgonine;

(31) "Nurse" means a person performing nursing as defined in section 20-87a;

(32) "Official written order" means an order for controlled substances written on a form provided by the bureau for that purpose under the Federal Controlled Substances Act;

(33) "Opiate" means any substance having an addiction-forming or addiction- sustaining liability similar to morphine or being capable of conversion into a drug having addiction-forming or addiction-sustaining liability; it does not include, unless specifically designated as controlled under this chapter, the dextrorotatory isomer of 3-methoxy-n-methylmorthinan and its salts (dextro-methorphan) but shall include its racemic and levorotatory forms;

(34) "Opium poppy" means the plant of the species papaver somniferum l., except its seed;

(35) "Osteopath" means a person authorized by law to practice osteopathy under section 20-17;

(36) "Other stimulant and depressant drugs" means controlled substances other than amphetamine-type, barbiturate-type, cannabis-type, cocaine-type, hallucinogenics and morphine-type which are found to exert a stimulant and depressant effect upon the higher functions of the central nervous system and which are found to have a potential for abuse and are controlled substances under this chapter;

(37) "Person" includes any corporation, association or partnership, or one or more individuals, government or governmental subdivisions or agency, business trust, estate, trust, or any other legal entity. Words importing the plural number may include the singular; words importing the masculine gender may be applied to females;

(38) "Pharmacist" means a person authorized by law to practice pharmacy pursuant to section 20-170, as amended by sections 15, 16 and 17 of Public Act 95-264 or section 20-172, as amended by section 18 of Public Act 95-264;

(39) "Pharmacy" means an establishment licensed pursuant to section 20-168;

(40) "Physician" means a person authorized by law to practice medicine in this state pursuant to sections 20-9 and 20-21;

(41) "Podiatrist" means a person authorized by law to practice podiatry in this state;

(42) "Poppy straw" means all parts, except the seeds, of the opium poppy, after mowing;

(43) "Practitioner" means: (A) A physician, dentist, veterinarian, podiatrist, osteopath, scientific investigator or other person licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance in the course of professional practice or research in this state; (B) a pharmacy, hospital or other institution licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance in the course of professional practice or research in this state;

(44) "Prescribe" means order or designate a remedy or any preparation containing controlled substances;

(45) "Prescription" means a written or oral order for any controlled substance or preparation from a licensed practitioner to a pharmacist for a patient;

(46) "Production" includes the manufacture, planting, cultivation, growing or harvesting of a controlled substance;

(47) "Registrant" means any person licensed by this state and assigned a current Federal Bureau of Narcotics and Dangerous Drug Registry Number as provided under the Federal Controlled Substances Act;

(48) "Registry number" means the alphabetical or numerical designation of identification assigned to a person by the Federal Drug Enforcement Administration, or other federal agency, which is commonly known as the federal registry number;

(49) "Restricted drugs or substances" are the following substances without limitation and for all purposes: Daturastramonium; hyoscyamus niger; atropa belladonna, or the alkaloids atropine; hyoscyamine; belladonnine; apatropine; or any mixture of these alkaloids such as daturine, or the synthetic homatropine or any salts of these alkaloids, except that any drug or preparation containing any of the above-mentioned substances which is permitted by federal food and drug laws to be sold or dispensed without a prescription or written order shall not be a controlled substance; amyl nitrite; the following volatile substances to the extent that said chemical substances or compounds containing said chemical substances are sold, prescribed, dispensed, compounded, possessed or controlled or delivered or administered to another person with the purpose that said chemical substances shall be breathed, inhaled, sniffed or drunk to induce a stimulant, depressant or hallucinogenic effect upon the higher functions of the central nervous system: Acetone; benzene; butyl alcohol; butyl nitrate and its salts, isomers, esters, ethers or their salts; cyclohexanone; dichlorodifluoromethane; ether; ethyl acetate; formaldehyde; hexane; isopropanol; methanol; methyl cellosolve acetate; methyl ethyl ketone; methyl isobutyl ketone; nitrous oxide; pentochlorophenol; toluene; toluol; trichloroethane; trichloroethylene; 1,4 butanediol.

(50) "Sale" is any form of delivery which includes barter, exchange or gift, or offer therefor, and each such transaction made by any person whether as principal, proprietor, agent, servant or employee;

(51) "State", when applied to a part of the United States, includes any state, district, commonwealth, territory or insular possession thereof, and any area subject to the legal authority of the United States of America;

(52) "State food, drug and cosmetic laws" means the Uniform Food, Drug and Cosmetic Act, section 21a-91 et seq.;

(53) "Ultimate user" means a person who lawfully possesses a controlled substance for his own use or for the use of a member of his household or for administering to an animal owned by him or by a member of his household;

(54) "Veterinarian" means a person authorized by law to practice veterinary medicine in this state;

(55) "Wholesaler" means a distributor or a person who supplies controlled substances that he himself has not produced or prepared to registrants as defined in subsection (47) of this section;

(56) "Reasonable times" means the time or times any office, care-giving institution, pharmacy, clinic, wholesaler, manufacturer, laboratory, warehouse, establishment, store or place of business, vehicle or other place is open for the normal affairs or business or the practice activities usually conducted by the registrant;

(57) "Unit dose drug distribution system" means a drug distribution system used in a hospital or chronic and convalescent nursing home in which drugs are supplied in individually labeled unit of use packages, each patient's supply of drugs is exchanged between the hospital pharmacy and the drug administration area or, in the case of a chronic and convalescent nursing home between a pharmacy and the drug administration area, at least once each twenty-four hours and each patient's medication supply for this period is stored within a patient-specific container, all of which is conducted under the direction of a pharmacist licensed in Connecticut and, in the case of a hospital, directly involved in the provision and supervision of pharmaceutical services at such hospital at least thirty-five hours each week;

(58) "Cocaine in a free-base form" means any substance which contains cocaine, or any compound, isomer, derivative or preparation thereof, in a nonsalt form.

Sec. 21a-241. (Formerly Sec. 19-449). Prior regulations continued. Regulations promulgated under chapter 344 of the general statutes, revision of 1958, as amended, and chapters 344a and 344b of the 1965 supplement thereto, in effect on October 1, 1967, shall, unless clearly in conflict with the provisions of this chapter, continue in effect until superseded by regulations hereunder.

Sec. 21a-242. (Formerly Sec. 19-450a). Schedules of controlled substances. Exceptions. Section 21a-242 is repealed.

Sec. 21a-243. (Formerly Sec. 19-451). Regulations re schedules of controlled substances. (a) The commissioner of consumer protection shall adopt regulations for the efficient enforcement and operation of sections 21a-244 to 21a-282, inclusive.

(b) The commissioner of consumer protection may, so far as may be consistent with said sections 21a-244 to 21a-282, inclusive, adopt the regulations existing under the Federal Controlled Substances Act and pertinent regulations existing under the federal food and drug laws and conform regulations adopted hereunder with those existing under the Federal Controlled Substances Act and federal food and drug laws.

(c) The commissioner of consumer protection acting upon the advice of the commission of pharmacy, may by regulation designate, after investigation, as a controlled substance, a substance or chemical composition containing any quantity of a substance which has been found to have a stimulant, depressant or hallucinogenic effect upon the higher functions of the central nervous system and having a tendency to promote abuse or physiological or psychological dependence or both. Such substances are classifiable as amphetamine-type, barbiturate-type, cannabis-type, cocaine-type, hallucinogenic, morphine-type and other stimulant and depressant substances, and specifically exclude alcohol, caffeine and nicotine. Substances which are designated as controlled

substances shall be classified in schedules I to V by regulations adopted pursuant to subsection (a) of this section.

(d) The commissioner of consumer protection may by regulation change the schedule in which a substance classified as a controlled substance in schedules I to V of the controlled substance scheduling regulations is placed. On or before December 15, 1986, and annually thereafter, the commissioner shall submit a list of all such schedule changes to the chairmen and ranking members of the joint standing committee of the general assembly having cognizance of matters relating to public health.

(e) A new or amended regulation under this chapter shall be adopted in accordance with the provisions of chapter 54.

(f) In the event of any inconsistency between the contents of schedules I, II, III, IV and V of the controlled substance scheduling regulations and schedules I, II, III, IV and V of the federal Controlled Substances Act, as amended, the provisions of the federal act shall prevail, except when the provisions of the Connecticut controlled substance scheduling regulations place a controlled substance in a schedule with a higher numerical designation, schedule I being the highest designation.

(g) When a drug which is not a controlled substance in schedule I, II, III, IV or V, as designated in the Connecticut controlled substance scheduling regulations, is designated to be a controlled substance under the federal Controlled Substances Act, such drug shall be considered to be controlled at the state level in the same numerical schedule for a period of two hundred forty days from the effective date of the federal classification.

Sec. 21a-244. (Formerly Sec. 19-451a). Regulations re storage and retrieval of prescription information. The commissioner of consumer protection shall, on or before January 1, 1978, adopt regulations governing the storage and retrieval of prescription information for controlled substances, including refills, by pharmacists through the use of electronic data processing systems or other systems for the efficient storage and retrieval of information.

Sec. 21a-244a. Regulations re use of electronic data processing systems for drug records. (a) The following terms shall have the following meanings when used in this section:

(1) "Drug" means (A) articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States or official National Formulary, or any supplement to any of them; (B) articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; (C) articles, other than food, intended to affect the structure or any function of the body of man or any other animal; and (D) articles intended for use as a component of any articles specified in this subdivision; but shall not include devices or their components, parts or accessories;

(2) "Licensed practitioner" means a person licensed by he state of Connecticut, any other state, the District of Columbia or the Commonwealth of Puerto Rico and authorized to prescribe medication within the scope of his practice;

(3) "Drug record" means a record of drug ordering, drug distribution, receipt of drugs, storage of drugs, disposition of drugs, and orders of drugs issued by a licensed practitioner for a patient.

(b) In lieu of maintaining written drug records required by state or federal law to be kept in the state, such records may be created and maintained on electronic data processing systems or other electronic media systems. If a conflict exists between maintaining a written drug record and maintaining an electronic drug record, the written drug record shall be maintained.

(c) Electronic identifiers, including, but not limited to, electronic codes or signatures, voice prints, retinal prints or handprints may be substituted in lieu of required written signatures or initials.

(d) The commissioner of consumer protection may adopt regulations in accordance with the provisions of chapter 54 of the general statutes, establishing the use of electronic data processing systems or other electronic media systems for maintaining drug records. No such electronic data processing system shall be implemented prior to the adoption of these regulations.

Sec. 21a-245. (Formerly Sec. 19-452). Manufacture, sale, administering of restricted substances regulated. No person shall manufacture, possess, have under his control, sell, prescribe, dispense, compound, process, deliver or administer to another person any restricted substance, except as authorized in this chapter and section 10-212a, except that no vendor of the volatile substances enumerated in subdivision (49) of section 21a-240 shall be deemed to have violated the provisions of this chapter insofar as sale, dispensing or delivering of one or more of said volatile substances or compounds containing said chemical substances is concerned, unless he knew or should have known of the improper purpose to which such substance was to be put. Insofar as substances containing said substances are possessed, sold, dispensed, compounded or delivered for licit purposes, i.e., other than to produce a stimulant, depressant or hallucinogenic effect upon the higher functions of the central nervous system by breathing, inhaling, sniffing or drinking, such substances are expressly not restricted and neither the regulatory provisions, including but not limited to record keeping, licensing and the writing of prescriptions nor the criminal sanctions and proscriptions of this chapter shall apply.

Sec. 21a-246. (Formerly Sec. 19-453). License to manufacture, wholesale, supply, compound, etc. Exception. License fees. License to possess and supply marihuana. (a) No person within this state shall manufacture, wholesale, repackage, supply, compound, mix, cultivate or grow, or by other process produce or prepare, controlled substances without first obtaining a license to do so from the commissioner of consumer protection and no person within this state shall operate a laboratory for the purpose of research or analysis using controlled substances without first obtaining a license to do so from the commissioner of consumer protection; provided such activities by pharmacists or pharmacies in the filling and dispensing of prescriptions or activities incident thereto, or the dispensing or administering of controlled substances by dentists, osteopaths, podiatrists, physicians, veterinarians, or other persons acting under their supervision, in the treatment of patients shall not be subject to the provisions of this section, and provided laboratories for instruction in dentistry, medicine, nursing, pharmacy, pharmacology and pharmacognosy in institutions duly licensed for such purposes in this state shall not be subject to the provisions of this section except with respect to narcotic drugs and schedule I and II controlled substances. Upon application of any physician licensed pursuant to chapter 370, the commissioner of consumer protection shall without unnecessary delay, license such physician to possess and supply marihuana for the treatment of glaucoma or the side effects of chemotherapy. No person without this state shall sell or supply controlled substances within the state without first obtaining a license to do so from the commissioner of consumer protection, provided no such license shall be required of a manufacturer whose principal place of business is located outside the state and who is registered with the federal Drug Enforcement Agency or other federal agency, and who files a copy of such registration with the appropriate licensing authority under this chapter.

(b) Such licenses shall expire on July first of each year, except licenses for the operation of a laboratory which shall expire on February first of each year, and may be renewed by application to the licensing authority. The commissioner of consumer protection following a hearing as prescribed in section 21a-275, may revoke or suspend any license granted by him pursuant to this section for violation of the provisions of any statute relative to controlled substances or of any regulation made hereunder. The licensing authority, upon application of any person whose license has been suspended or revoked, may reinstate such license upon a showing of good cause.

(c) The fee for licenses provided pursuant to this section shall be according to the following schedule: For any wholesaler, one hundred fifty dollars per annum; for manufacturers employing not more than five licensed pharmacists or qualified chemists or both, two hundred twenty-five dollars per annum; for manufacturers employing six to ten licensed pharmacists or qualified chemists or both, three hundred dollars per annum; for manufacturers employing more than ten licensed pharmacists or qualified chemists or both, seven hundred fifty dollars per annum; for laboratories, forty dollars per annum. A separate fee is required for each place of business or professional practice where the licensee uses, manufactures, stores, distributes, analyzes or dispenses controlled drugs.

(d) Controlled substances which are possessed, kept or stored at an address or location other than the address or location indicated on the registration required by chapter 420c or by federal laws and regulations shall be deemed to be possessed, kept or stored illegally and shall be subject to seizure and forfeited to the state. The following are subject to forfeitures: (1) All controlled substances which have been manufactured, distributed, dispensed or acquired in violation of this chapter; (2) all raw materials, products and equipment of any kind which are used, or intended for use, in manufacturing, compounding, processing, delivering, importing, or exporting any controlled substance in violation of this chapter; (3) all property which is used, or intended for use, as a container for property described in paragraph (1) or (2); (4) all conveyances, including aircraft, vehicles or vessels, which are used, or intended for use, to transport or in any manner to facilitate the transportation, for the purpose of sale or receipt of property described in paragraph (1) or (2), but (i) no conveyance used by any person as a common carrier is subject to forfeiture under this chapter unless it appears that the owner or other person in charge of the conveyance is a consenting party or privy to a violation of this chapter; (ii) no conveyance is subject to forfeiture under this chapter by reason of any act or omission established by the owner thereof to have been committed or omitted without his knowledge or consent.

Sec. 21a-247. (Formerly Sec. 19-454). Qualifications of applicant for license. No license shall be issued under section 21a-246 until the applicant therefor has furnished proof satisfactory to the licensing authority (1) that the applicant is of good moral character or, if the applicant is an association or corporation, that the managing officers are of good moral character and (2) that the applicant is equipped as to facilities and apparatus properly to carry on the business described in his application and (3) that the applicant conforms to regulations adopted and promulgated pursuant to section 21a-243. No license shall be granted to any person who has, within five years of the date of application, been convicted of a violation of any law of the United States, or of any state, relating to a controlled drug.

Sec. 21a-248. (Formerly Sec. 19-456). Sale or dispensing of controlled drugs by licensed manufacturer or wholesaler. Records; orders. Scope of uses limited. (a) A licensed manufacturer or wholesaler may sell and dispense controlled drugs to any of the following-named persons, but in the case of schedule II drugs only on official written order: (1) To a manufacturer, wholesaler or pharmacist; (2) to a physician, dentist or veterinarian; (3) to a person in charge of a hospital, incorporated college or scientific institution, but only for use by or in that hospital, incorporated college or scientific institution for medical or scientific purposes; (4) to a person in charge of a laboratory, but only for use in that laboratory for scientific and medical purposes; (5) to any registrant as defined in subdivision (47) of section 21a-240.

(b) A licensed manufacturer or wholesaler may sell controlled drugs only to registrants when permitted under federal and state laws and regulations.

(c) An official written order for any schedule I or II drug shall be signed in triplicate by the person giving such order or by his authorized agent and the original shall be presented to the person who sells or dispenses the drug or drugs named therein as provided by federal laws. If such order is

accepted by such person, each party to the transaction shall preserve his copy of such order for a period of three years in such a way as to be readily accessible for inspection by any public officer or employee engaged in the enforcement of this chapter.

(d) The manufacturer or wholesaler shall keep records of all sales and dispensing of controlled drugs and shall comply fully with applicable provisions of the federal controlled drug laws and the federal food and drug laws, and the state food, drug and cosmetic laws in such sale or dispensing of controlled drugs.

(e) Possession or control of controlled drugs obtained as authorized by this section shall be lawful only if obtained in the regular course of the business, occupation, profession, employment or duty of the possessor.

(f) A person in charge of a hospital, incorporated college or scientific institution, or of a laboratory, or in the employ of this state or of any other state, or of any political subdivision thereof, and a master or other proper officer of a ship or aircraft, who obtains controlled drugs under the provisions of this section or otherwise, shall not administer, or dispense, or otherwise use such drugs within this state, except within the scope of his employment or official duty, and then only for scientific or medicinal purposes or for the purposes of research or analysis and subject to the provisions of this chapter.

Sec. 21a-249. (Formerly Sec. 19-457). Prescription requirements. (a) All prescriptions for controlled drugs shall include (1) the name and address of the patient, or the name and address of the owner of an animal and the species of the animal, (2) whether the patient is an adult or a child, or his specific age, (3) the compound or preparation prescribed and the amount thereof, (4) directions for use of the medication, (5) the name and address of the prescribing practitioner, (6) the date of issuance and (7) the Federal Registry number of the practitioner. No prescription blank containing a prescription for a Schedule II substance shall contain more than one prescription.

(b) Prescriptions when written shall be written in ink or in indelible pencil or by typewriter. No duplicate, carbon or photographic copies and no printed or rubber-stamped orders shall be considered valid prescriptions within the meaning of this chapter. No prescription or order for any controlled substance issued by a practitioner to an inanimate object or thing shall be considered a valid prescription within the meaning of this chapter.

(c) Prescriptions for schedule II substances shall be signed by the prescribing practitioner at the time of issuance and previously signed orders for such Schedule II substances shall not be considered valid prescriptions within the meaning of this chapter. No practitioner may prescribe, dispense or administer Schedule II sympathomimetic amines as anorectics, except as may be authorized by regulations adopted by the Departments of Health Services and Consumer Protection acting jointly. The Department of Health Services and the Department of Consumer Protection, acting jointly, may adopt regulations, in accordance with Chapter 54, allowing practitioners to prescribe, dispense or administer Schedule II sympathomimetic amines as anorectics under specific circumstances. Nothing in this subsection shall be construed to require a licensed pharmacist to determine the diagnosis of a patient prior to dispensing a prescription for such substances to a patient.

(d) To the extent permitted by the federal controlled substances act, 21 USC 801, as amended from time to time, a prescribing practitioner may issue an oral order or an electronically transmitted prescription order and, except as otherwise provided by regulations adopted pursuant to sections 21a-243 and 21a-244, such oral order or electronically transmitted prescription order shall be promptly reduced to writing on a prescription blank or a hardcopy printout shall be produced and filed by the pharmacist filling it. For purposes of subsections (d) and (h) of this section the term “Electronically transmitted” means transmitted by facsimile machine, computer modem or other similar electronic device.

(e) To the extent permitted by the Federal Controlled Substances Act, in an emergency the dispensing of Schedule II substances, may be made upon the oral order of a prescribing registrant known to or confirmed by the filling pharmacist who shall promptly reduce the oral order to writing on a prescription blank, provided in such cases such oral order shall be confirmed by the proper completion and mailing or delivery of a prescription prepared by the prescribing registrant to the pharmacist filling such oral order within seventy-two hours after the oral order has been given. Such prescription of the registrant shall be affixed to the temporary prescription prepared by the pharmacist and both prescriptions shall be maintained on file as required in this chapter.

(f) All prescriptions for controlled substances shall comply fully with any additional requirements of the federal food and drug laws, federal laws and regulations Part 306, U.S. Department of Justice, Bureau of Narcotics and Dangerous Drugs Federal Register Volume 36 No. 80 et seq., and state laws and regulations adopted under this chapter.

(g) Repealed by P.A. 82-419, S. 46, 47.

(h) Except when dispensed directly by a practitioner, other than a pharmacy, to an ultimate user, a controlled substance included in Schedule III or IV, which is a prescription drug as determined under federal food and drug laws, shall not be dispensed without a written, electronically transmitted or oral prescription of a practitioner. The prescription shall not be filled or refilled more than six months after the date thereof or be refilled more than five times, unless renewed by the practitioner.

(i) A controlled substance included in Schedule V shall not be distributed or dispensed other than for a medical purpose.

(j) A pharmacy may sell and dispense controlled substances upon the prescription of a prescribing practitioner, as defined in subdivision (22) of section 20-571.

(k) Pharmacies shall file filled prescriptions for controlled substances separately from other prescriptions. All Schedule II prescriptions shall be filed in a separate file. All Schedule III, IV and V prescriptions shall be filed in another separate file except as otherwise provided for in regulations adopted pursuant to section 21a-244. Such controlled substance prescriptions shall, immediately upon filling, be filed chronologically and consecutively.

(l) Any pharmacy may transfer prescriptions for controlled substances included in schedules III, IV and V to any other pharmacy in accordance with the requirements set forth in the federal Controlled Substances Act 21 USC 801 et seq. and the regulations promulgated thereunder, as from time to time amended.

(m) A practitioner authorized to prescribe controlled substances shall not prescribe anabolic steroids for the sole purpose of enhancing a patient's athletic ability or performance.

Sec. 21a-250. (Formerly Sec. 19-458). Rights and duties of pharmacist. (a) A pharmacist, in good faith, may sell and dispense controlled substances to any person upon a prescription of a physician or of an osteopath, dentist, podiatrist, optometrist, veterinarian, physician assistant licensed pursuant to section 20-12b, advanced practice registered nurse, or nurse-midwife to the extent that they are authorized to prescribe such controlled substances. Except as otherwise provided by regulations adopted pursuant to section 21a-244, the person filling or refilling the prescription shall include the date of filling and his signature or initials on any prescription for controlled substances, and the prescription shall be retained on file by the proprietor of the pharmacy in which it is filled for a period of three years, so as to be readily accessible for inspection by any public officer or employee engaged in the enforcement of this chapter. The prescription shall not be filled or refilled unless permitted by federal food and drug laws, the Federal Controlled Substances Act, and regulations adopted under this chapter.

(b) The legal owner of any stock of controlled substances in a pharmacy, upon discontinuance of dealing in such substances, may sell such stock to a manufacturer, distributor, practitioner, wholesaler or pharmacy, but schedule II substances may only be sold on such written order as is required by the Federal Controlled Substances Act.

(c) A pharmacist, only upon an official written order, may sell to a registrant the kinds and quantities of aqueous or oleaginous schedule ii substances which he has prepared and which are permitted by the Federal Controlled Substances Act.

(d) (1) A retail pharmacy or pharmacy within a licensed hospital may distribute small quantities of schedule III, IV or V controlled substances to another pharmacy to provide for the immediate needs of a patient pursuant to a prescription or medication order of a practitioner. As used in this subsection "small quantities" means not more than one ounce of a powder or ointment, not more than sixteen ounces of a liquid and not more than one hundred dosage units of tablets, capsules, suppositories or injectables.

(2) A retail pharmacy may distribute, in accordance with state and federal statutes and regulations, a schedule II, III, IV or V controlled substance to a practitioner who has a current federal and state registry number authorizing such practitioner to purchase such controlled substances, and who is the medical director of a chronic and convalescent nursing home , of a rest home with nursing supervision or of a state correctional institution, for use as emergency stock within such facility. Such drugs shall be supplied in containers which bear labels specifying the name of the drug and its strength, expiration date, lot number and manufacturer. Drugs supplied pursuant to this subsection shall be limited in type and quantity to those specifically documented and authorized by such medical director for use as emergency stock in such facility. (3) Pharmacies distributing controlled substances in accordance with the provisions of subdivisions (1) and (2) of this subsection shall keep a written record of such transactions containing the name of the receiving pharmacy, or the name and federal registry number of a medical director, date distributed and name, form, strength and quantity of such controlled substances distributed. Such records shall be kept on file separately, in accordance with subsection (h) of section 21a-254. Receiving pharmacies or medical directors, shall keep, in a separate file, a written record in accordance with subsections (f) and (h) of section 21a-254.

Sec. 21a-250a. Transferred to Chapter 417, Sec. 21a-70a.

Sec. 21a-251. (Formerly Sec. 19-459). Dispensing of controlled substances by hospitals, infirmaries or clinics. (a)No controlled substances shall be dispensed or administered by hospitals, infirmaries or clinics except upon written order signed or initialed by the prescribing practitioner or upon an oral order of a prescribing practitioner which shall be confirmed by a written order which shall be signed or initialed by such prescribing practitioner within twenty-four hours after the giving of such oral order for schedule II controlled substances and within seventy-two hours after the giving of such oral order for other controlled substances.

(b) Original and continuing orders for schedule II controlled substances shall be limited to a period not exceeding seven days from the time the order is entered, but may be extended for additional periods of seven days each by the signing or initialing of the order by a prescribing practitioner.

(c) Original and continuing orders for schedule III, IV or V controlled substances shall be limited in duration as designated in the written order of the prescribing practitioner, but in no case shall such order be effective for more than thirty days.

(d) An original or continuing medication order for a controlled substance in a hospital, as defined in subsection (b) of section 19a-490, as amended, or a hospice licensed by the department of public health or certified pursuant to 42 USC section 1395x, may include a range of doses that may be administered by a physician assistant licensed pursuant to chapter 370, a licensed nurse or an

advanced practice registered nurse licensed pursuant to chapter 378 or a nurse-midwife licensed pursuant to chapter 377. Each such hospital or hospice shall establish a written protocol that identifies the specific drugs that may be prescribed in ranges and that lists critical assessment parameters and guidelines to be considered in implementing such orders. The commissioner of consumer protection, with the advice and assistance of the commissioner of any other state health care licensing authority having primary jurisdiction over such hospital or hospice, may require the modification of any protocol to meet the requirements of this subsection. Nothing in this subsection shall be construed to restrict the use of patient administered analgesia through the use of pumps or similar devices.

Sec. 21a-252. (Formerly Sec. 19-460). Prescription and dispensing of controlled substances by certain practitioners. Surrender of unused substances by patients. (a) A physician, in good faith and in the course of his professional practice only, may prescribe, administer and dispense controlled substances or he may cause the same to be administered by a physician assistant, nurse or intern under his direction and supervision, for demonstrable physical or mental disorders but not for drug dependence except in accordance with state and federal laws and regulations adopted thereunder. Notwithstanding the provisions of this subsection the department of consumer protection may approve protocols allowing the dispensing of take home doses of methadone, by a registered nurse or licensed practical nurse, to outpatients in duly licensed substance abuse treatment facilities. Such dispensing shall be done pursuant to the order of a licensed prescribing practitioner and using computerized dispensing equipment into which bulk supplies of methadone are dispensed by a pharmacist. The quantity of methadone dispensed by such nurse shall not exceed at any one time that amount allowed under federal or state statutes or regulations governing the treatment of drug dependent patients. The department of consumer protection shall conduct inspections of such treatment facilities to ensure that the computerized equipment and related dispensing procedures documented in the approved protocols are adhered to.

(b) An osteopath, in good faith and in the course of his professional practice only, may prescribe, administer or dispense controlled substances or he may cause the same to be administered by a nurse under his direction and supervision, for relief of pain to the extent permitted by the Federal Controlled Substances Act and state laws and regulations relating to osteopathy.

(c) A dentist, in good faith and in the course of his professional practice only, may prescribe, administer or dispense controlled substances or he may cause the same to be administered by a nurse under his direction and supervision, to the extent permitted by the Federal Controlled Substances Act, federal food and drug laws and state laws and regulations relating to dentistry.

(d) A podiatrist, in good faith and in the course of his professional practice only, may prescribe, administer and dispense controlled substances in schedules II, III, IV or V or he may cause the same to be administered by a nurse under his direction and supervision, to the extent permitted by the Federal Controlled Substances Act, the federal food and drug laws and state laws and regulations relating to podiatry.

(e) A veterinarian, in good faith in the course of his professional practice only, and not for use by a human being, may prescribe, administer and dispense controlled substances, and he may cause them to be administered by an assistant or orderly under his direction and supervision, to the extent permitted by the Federal Controlled Substances Act, the federal food and drug laws and state laws and regulations relating to veterinary medicine.

(f) An advanced practice registered nurse licensed pursuant to section 20-94a, as amended, in good faith and in the course of his professional practice only, may prescribe, dispense, and administer controlled substances in schedule II, III, IV or V or may cause the same to be administered by a registered nurse or licensed practical nurse under his direction and supervision, to the extent permitted by the federal Controlled Substances Act, the federal food and drug laws and state laws and regulations relating to advanced nursing practice.

(g) A nurse-midwife licensed under chapter 377, in good faith and in the course of his professional practice only, may prescribe, dispense, and administer controlled substances in schedules II, III, IV and V or he may cause the same to be administered by a registered nurse or licensed practical nurse under his direction and supervision, to the extent permitted by the federal Controlled Substances Act, the federal food and drug laws and state laws.

(h) A physician assistant licensed pursuant to section 20-12b, as amended, in good faith and in the course of his professional practice only, may prescribe, dispense, and administer controlled substances in schedule II, III, IV or V, or may cause the same to be administered by an advanced practice registered nurse, registered nurse, or licensed practical nurse who is acting under a physician's direction, to the extent permitted by the Federal Controlled Substances Act, the federal food and drug laws and state laws and regulations relating to physician assistant practice.

(i) An optometrist authorized to practice advanced optometrical care, in good faith and in the course of his professional practice only and who is duly authorized by section 20-127, as amended by section 1 of public act 96-70 may prescribe, administer or dispense controlled substances in schedules II, III, IV or V to the extent permitted by the federal controlled substances act, the federal food and drug laws and state laws and regulations relating to optometry.

(j) Any person who has obtained directly from a physician, osteopath, dentist, podiatrist, veterinarian, physician assistant, advanced practice registered nurse or nurse-midwife any controlled substance for administration to himself or to a patient during the absence of such physician, osteopath, dentist, podiatrist, veterinarian, physician assistant, advanced practice registered nurse or nurse-midwife shall return to such physician, osteopath, dentist, podiatrist, optometrist, veterinarian, physician assistant, advanced practice registered nurse or nurse-midwife any unused portion of such controlled substance, when it is no longer required by him or the patient, or he may surrender such controlled substance to the commissioner of consumer protection for proper disposition.

Sec. 21a-253. Possession of marihuana pursuant to a prescription by a physician. Any person may possess or have under his control a quantity of marihuana less than or equal to that quantity supplied to him pursuant to a prescription made in accordance with the provisions of section 21a-249 by a physician licensed under the provisions of chapter 370 and further authorized by subsection (a) of section 21a-246 by the commissioner of consumer protection to possess and supply marihuana for the treatment of glaucoma or the side effects of chemotherapy.

Sec. 21a-254. (Formerly Sec. 19-461). Designation of restricted drugs or substances by regulations. Records required by chapter. (a) The commissioner of consumer protection, after investigation and hearing, may by regulation designate certain substances as restricted drugs or substances by reason of their exceptional danger to health or exceptional potential for abuse so as to require written records of receipt, use and dispensation, and may, after investigation and hearing, remove the designation as restricted drugs or substances from any substance so previously designated.

(b) Each physician, dentist, veterinarian or other person who is authorized to administer or professionally use Schedule I substances shall keep a record of such Schedule I substances received by him and a record of all such Schedule I substances administered, dispensed or professionally used by him. The record of Schedule I substances received shall in each case show the date of receipt, the name and address of the person from whom received and the kind and quantity of Schedule I substances received. The record of all Schedule I substances administered, dispensed or otherwise disposed of shall show the date of administering or dispensing, the name and address of the person to whom, or for whose use, or the owner and species of animal for which, the substances were administered or dispensed and the kind and quantity of substances.

(c) Practitioners obtaining and dispensing controlled substances shall keep a record of all such controlled substances, received and dispensed by them in accordance with the provisions of subsections (f) and (h) of this section.

(d) Manufacturers and wholesalers shall keep records of all controlled substances, compounded, mixed, cultivated or grown, or by any other process produced or prepared, and of all controlled substances received and disposed of by them in accordance with the provisions of subsections (f) and (h) of this section.

(e) Pharmacies, hospitals, chronic and convalescent nursing homes, rest homes with nursing supervision, clinics, infirmaries, free-standing ambulatory surgical centers and laboratories shall keep records of all controlled substances, received and disposed of by them in accordance with the provisions of subsections (f) and (h) of this section, except that hospitals and chronic and convalescent nursing homes using a unit dose drug distribution system may instead keep such records in accordance with the provisions of subsections (g) and (h) of this section, and except that hospitals and free-standing ambulatory surgical centers shall not be required to maintain separate disposition records for Schedule V controlled substances or records of administering of individual doses for ultra-short-acting depressants, including but not limited to, Methohexital, Thiamylal and Thiopental.

(f) The form of record to be kept under subsection (c), (d) or (e) of this section shall in each case show the date of receipt, the name and address of the person from whom received, and the kind and quantity of controlled substances received, or, when applicable, the kind and quantity of controlled substances produced or removed from process of manufacture and the date of such production or removal from process of manufacture; and the record shall in each case show the proportion of controlled substances. The record of all controlled substances sold, administered, dispensed or otherwise disposed of shall show the date of selling, administering or dispensing, the name of the person to whom or for whose use, or the owner and species of animal for which, the substances were sold, administered or dispensed, the address of such person or owner in the instance of records of other than hospitals, chronic and convalescent nursing homes, rest homes with nursing supervision and infirmaries, and the kind and quantity of substances. In addition, hospital and infirmary records shall show the time of administering or dispensing, the prescribing physician and the nurse administering or dispensing the substance. Each such record of controlled substances shall be separately maintained apart from other drug records and kept for a period of three years from the date of the transaction recorded.

(g) Hospitals using a unit dose drug distribution system shall maintain a record noting all dispositions of controlled substances from any area of the hospital to other hospital locations. Such record shall include, but need not be limited to, the name, form, strength and quantity of the drug dispensed, the date dispensed and the location within the hospital to which the drug was dispensed. Such dispensing record shall be separately maintained, apart from other drug or business records, for a period of three years. Such hospital shall, in addition, maintain for each patient a record which includes, but need not be limited to, the full name of the patient and a complete description of each dose of medication administered, including the name, form, strength and quantity of the drug administered, the date and time administered and identification of the nurse or practitioner administering each drug dose. Entries for controlled substances shall be specially marked in a manner which allows for ready identification. Such records shall be filed in chronological order and kept for a period of three years.

(h) A complete and accurate record of all stocks of controlled substances on hand shall, on and after July 1, 1981, be prepared biennially within four days of the first day of May of the calendar year, except that a registrant may change this date provided the general physical inventory date of such registrant is not more than six months from the biennial inventory date, and kept on file for three years; and shall be made available to the commissioner or his authorized agents. The keeping of a record required by or under the Federal Controlled Substances Act, or federal food and

drug laws, containing substantially the same information as is specified above, shall constitute compliance with this section, provided each record shall in addition contain a detailed list of any controlled substances lost, destroyed or stolen, the kind and quantity of such substances and the date of the discovery of such loss, destruction or theft and provided such record shall be made available to the commissioner or his authorized agents. All records required by this chapter shall be kept on the premises of the registrant and maintained current and separate from other business records in such form as to be readily available for inspection by the authorized agent at reasonable times. The use of a foreign language, codes or symbols to designate controlled substances or persons in the keeping of any required record is not deemed to be a compliance with this chapter.

(i) Whenever any record is removed by a person authorized to enforce the provisions of this chapter or the provisions of the state food, drug and cosmetic laws for the purpose of investigation or as evidence, such person shall tender a receipt in lieu thereof and the receipt shall be kept for a period of three years.

Sec. 21a-255. (Formerly Sec. 19-462). Penalty for failure to keep or furnish records, statements, information. (a) Any person who, either as principal or agent, refuses or fails to make, furnish or keep any record, notification, order form, statement, invoice or information required by sections 21a-243 to 21a-282, inclusive, or regulations adopted pursuant to section 21a-244, for the first offense may be fined not more than five hundred dollars and for each subsequent offense may be fined not more than one thousand dollars or imprisoned not more than thirty days or be both fined and imprisoned.

(b) Any person who fails to keep any record required by said sections 21a-243 to 21a-282, inclusive, or said regulations, with an intent to defeat the purpose of this chapter or any person who violates any other provision of said sections, except as to such violations for which penalties are specifically provided in sections 21a-277 and 21a-279, may, for the first offense, be fined not more than one thousand dollars or be imprisoned for not more than two years or be both fined and imprisoned; and for the second and each subsequent offense may be fined not more than ten thousand dollars or be imprisoned not more than ten years or be both fined and imprisoned.

Sec. 21a-256. (Formerly Sec. 19-463). Labeling of package or container of controlled substances. (a) When a manufacturer sells or dispenses a controlled substance and when a wholesaler sells, dispenses or distributes a controlled substance in a package prepared by him, he shall securely affix to each package in which that substance is contained a label showing in legible English the name and address of the vendor and the quantity, kind and form of controlled substance contained therein and any additional information required under the federal food and drug laws and the state food, drug and cosmetic laws. No person, except a practitioner dispensing a controlled substance under this chapter, shall alter, deface or remove any label so affixed.

(b) When a pharmacist sells or dispenses any controlled substance on prescription issued by a physician, advanced practice registered nurse, physician assistant, podiatrist, osteopath, dentist or veterinarian, he shall affix, to the container in which such substance is sold or dispensed, a label showing the name and address of the pharmacy for which he is lawfully acting, the full name of the patient, or, if the patient is an animal, the name of the owner of the animal and the species of the animal, the last name of the physician, advanced practice registered nurse, physician assistant, osteopath, podiatrist, dentist or veterinarian by whom the prescription was written, such directions as may be stated on the prescription, the serial number of the prescription, the date of filling or refilling and any cautionary statement in such prescription as may be required by law.

(c) When aqueous or oleaginous preparations are sold under subsection (c) of section 21a-250, a label shall be affixed to the container containing the preparation which bears the name, address and BNDD numbers of the vendor and vendee, the date of sale, the kind and quantity of

substance sold and the serial number of the official written order. No person shall alter, deface or remove any label affixed pursuant to subsection (b) or this subsection.

Sec. 21a-257. (Formerly Sec. 19-464). Person receiving narcotic drug to keep it in original container. A person to whom or for whose use any narcotic drug has been prescribed, sold or dispensed by a physician, osteopath, dentist, pharmacist or other person authorized under the provisions of section 21a-248, and the owner of any animal for which any such drug has been prescribed, sold or dispensed may lawfully possess it only in the container in which it was delivered to him by the person selling or dispensing the same except as may be authorized by regulations adopted hereunder.

Sec. 21a-258. (Formerly Sec. 19-465). Exceptions concerning possession and control. The provisions of this part restricting the possession and control of controlled substances shall not apply to common carriers or to warehousemen, while engaged in lawfully transporting or storing such substances, or to any employee of the same acting within the scope of his employment; or to public officers or employees in the performance of their official duties requiring possession or control of controlled substances; or to temporary incidental possession by employees or agents of persons lawfully entitled to possession or by persons whose possession is for the purpose of aiding public officers in performing their official duties.

Sec. 21a-259. (Formerly Sec. 19-466). Common nuisances. Any store, shop, warehouse, dwelling house, building, vehicle, boat, aircraft or any place whatever, other than as authorized by law, which is frequently resorted to by drug-dependent persons for the purpose of using controlled substances or which is used for the illegal keeping or selling of the same, shall be deemed a common nuisance.

Sec. 21a-260. (Formerly Sec. 19-467a). Narcotics control section in department of consumer protection. The narcotics control section of the department of health services shall be merged into the department of consumer protection.

Sec. 21a-261. (Formerly Sec. 19-468). Inspection of records. Entry on premises. Warrants and arrests. (a) Every person required by section 21a-254 to prepare or obtain and keep records of controlled substances, and any carrier maintaining records with respect to any shipment containing any controlled substance, and every person in charge, or having custody, of such records shall, upon request of the commissioner of consumer protection and his authorized agents, permit said commissioner and his authorized agents at reasonable times to have access to and copy such records.

(b) For the purposes of verification of such records and of the enforcement of this part, said commissioner and his agents, are authorized to enter, at reasonable times, any place, clinic, infirmary, correctional institution, care-giving institution, pharmacy, drug room, office, hospital, laboratory, factory, warehouse, establishment or vehicle in which any controlled substance is held, manufactured, compounded, processed, sold, delivered or otherwise disposed of and to inspect, within reasonable limits and in a reasonable manner, such place, clinic, infirmary, correctional institution, care-giving institution, pharmacy, drug room, office, hospital, laboratory, factory, warehouse, establishment or vehicle, and all pertinent equipment, finished and unfinished material, containers and labeling, and all things therein including records, files, papers, processes, controls and facilities, and to inventory any stock of any such controlled substance therein and obtain samples of any such substance, any labels or containers for such substance and of any finished and unfinished material.

(c) No inspection authorized by subsection (b) shall extend to (1) financial data, (2) sales data other than shipment data, (3) pricing data, (4) personnel data or (5) research data and secret processes or apparatus.

(d) The commissioner of consumer protection and his authorized agents are authorized and empowered to obtain and serve search warrants and arrest warrants; to seize contraband controlled substances; and to make arrests without warrant for offenses under sections 21a-243 to 21a-282, inclusive, if the offense is committed in their presence or, in the case of a felony, if they have probable cause to believe that the person so arrested has committed, or is committing, such offense. The commissioner and his authorized agents when executing the powers authorized pursuant to this subsection, except when using deadly physical force, shall be deemed to be acting in the capacity of a peace officer as defined in subsection (9) of section 53a-3.

Sec. 21a-262. (Formerly Sec. 19-469). Commissioner's authority and duties re controlled substances. When seizing authority may destroy. The commissioner of consumer protection may receive, take into custody or destroy excess or undesired controlled substances and may in his discretion deliver, upon application, to any hospital, laboratory, incorporated college, scientific institution or any state or municipal agency or institution not operated for private gain, any controlled substances that have come into his custody by authority of this section. In the case of a care-giving or correctional or juvenile training institution having an institutional pharmacy, the commissioner of consumer protection shall deliver such controlled substances only to the licensed pharmacist in charge of such pharmacy. The commissioner of consumer protection may receive and take into custody excess or undesired controlled substances from pharmacists, manufacturers and wholesalers or any other registrant. Said commissioner shall keep a full and complete record of all substances received and of all substances disposed of, showing the exact kinds, quantities and forms of such substances, the persons from whom received and to whom delivered, by whose authority received, delivered and destroyed, and the dates of the receipt, disposal or destruction. Controlled substances and preparations shall at all times be properly safeguarded and securely kept. Minimum security and safeguard standards for the storage, manufacture, sale or distribution of all controlled substances shall be established by regulations adopted hereunder. Controlled substances seized or held as contraband or controlled substances, the title to which cannot be resolved, which controlled substances are not held by law enforcement agencies or court officials as evidence in criminal proceedings, shall be, upon the order of the court, destroyed by the seizing authority or delivered to the commissioner of consumer protection as soon as possible upon resolution of the case or upon ascertaining the status of the unclaimed substance. The agent of the commissioner of consumer protection shall issue a receipt for all such substance obtained. Any loss, destruction or theft of controlled substances shall be reported by a registrant within seventy-two hours to the commissioner of consumer protection as follows: (1) Where, through breakage of the container or other accident, otherwise than in transit, controlled substances are lost or destroyed, the person having title thereto shall make a signed statement as to the kinds and quantities of controlled substances lost or destroyed and the circumstances involved, and immediately forward the statement to the commissioner of consumer protection. A copy of such statement shall be retained by the registrant. (2) Where controlled substances are lost by theft, or otherwise lost or destroyed in transit, the consignee shall, immediately upon ascertainment of the occurrence, file with the commissioner of consumer protection a signed statement of the facts, including a list of the controlled substances stolen, lost or destroyed and documentary evidence that the local authorities were notified. A copy of the statement shall be retained by the registrant. As used in this section, "Care-giving institution", "Correctional or juvenile training institution", "Institutional pharmacy" and "Pharmacist" shall have the same meaning as used in section 20-184a, as amended by section 2 of Public Act 95-264.

(b) For each long-term care facility, two or more of the following persons may jointly dispose of excess stock of controlled substances: A nursing home administrator, a pharmacist consultant, a director of nursing services or an assistant director of nursing services. Such facility shall maintain documentation of any such destruction and disposal for a period of three years and such documentation shall be maintained in a separate log and on a form prescribed by the department.

(c) For each outpatient surgical facility, as defined in section 19a-493b, two or more of the following persons may jointly dispose of excess stock of controlled substances: An administrator, a clinical director or chief of staff, or a nursing supervisor. Such facility shall maintain documentation of any such destruction and disposal for a period of three years and such documentation shall be maintained in a separate log and on a form prescribed by the department.

Sec. 21a-263. (Formerly Sec. 19-469a). Power of commissioner to receive and destroy drug paraphernalia. Records. The commissioner of consumer protection may receive, take into custody or destroy any drug paraphernalia as defined in subdivision (20) of section 21a-240. Said commissioner shall keep a full and complete record of all drug paraphernalia received and disposed of, showing the exact kinds, quantities and forms of such drug paraphernalia, the persons from whom received, by whose authority received and destroyed, and the dates of the receipt or destruction. Drug paraphernalia held by law enforcement agencies or court officials as evidence in criminal proceedings, or drug paraphernalia seized or held as contraband shall be destroyed upon the order of the court by the seizing authority or delivered to the commissioner of consumer protection as soon as possible upon termination of the proceedings or resolution of the case.

Sec. 21a-264. (Formerly Sec. 19-470). Notice to licensing boards of violations by licensees. On the conviction of any person of the violation of any provision of this part, a copy of the judgment and sentence and of the opinion of the court, if any opinion is filed, shall be sent by the clerk of the court, or by the judge, to the board or officer, if any, by whom such person has been licensed or registered to practice his profession or to carry on his business and the court may, in its discretion, recommend to the licensing or registering board or officer that the license or registration of such person to practice his profession or to carry on his business be suspended or revoked. On the application of any person whose license or registration has been so suspended or revoked, such board or officer may, for good cause shown, reinstate such license or registration.

Sec. 21a-265. (Formerly Sec. 19-471). Inspection of prescriptions, orders, records and stocks restricted to government officers and third-party payors. Confidentiality. Prescriptions, orders and records required by sections 21a-243 to 21a-282, inclusive, and stocks of controlled substances shall be open for inspection only to federal, state, county and municipal officers, whose duty it is to enforce the laws of this state or of the United States relating to controlled substances, and to third party payors having a formal agreement or contract to audit such prescriptions, orders and records in connection with claims submitted to such payors. No such officer or third party payor having knowledge by virtue of his office of any such prescription, order or record shall divulge such knowledge, except in connection with a civil action or criminal prosecution in court or before a licensing or registration board or officer, to which action, prosecution or proceeding the person to whom such prescriptions, orders or records relate is a party.

Sec. 21a-266. (Formerly Sec. 19-472). Prohibited acts. (a) No person shall obtain or attempt to obtain a controlled substance or procure or attempt to procure the administration of a controlled substance (1) by fraud, deceit, misrepresentation or subterfuge, or (2) by the forgery or

alteration of a prescription or of any written order, or (3) by the concealment of a material fact, or (4) by the use of a false name or the giving of a false address.

(b) Information communicated to a practitioner in an effort unlawfully to procure a controlled substance, or unlawfully to procure the administration of any such substance, shall not be deemed a privileged communication.

(c) No person shall wilfully make a false statement in any prescription, order, report or record required by this part.

(d) No person shall, for the purpose of obtaining a controlled substance, falsely assume the title of, or represent himself to be, a manufacturer, wholesaler, pharmacist, physician, dentist, osteopath, veterinarian, podiatrist or other authorized person.

(e) No person shall make or utter any false or forged prescription or false or forged written order.

(f) No person shall affix any false or forged label to a package or receptacle containing controlled substances.

(g) No person shall alter an otherwise valid written order or prescription except upon express authorization of the issuing practitioner.

(h) No person who, in the course of treatment, is supplied with controlled substances or a prescription therefor by one practitioner shall, knowingly, without disclosing such fact, accept during such treatment controlled substances or a prescription therefor from another practitioner with intent to obtain a quantity of controlled substances for abuse of such substances.

(i) The provisions of subsections (a), (d) and (e) shall not apply to manufacturers of controlled substances, or their agents or employees, when such manufacturers or their authorized agents or employees are actually engaged in investigative activities directed toward safeguarding of the manufacturer's trademark, provided prior written approval for such investigative activities is obtained from the commissioner of consumer protection.

Sec. 21a-267. (Formerly Sec. 19-472a). Prohibited acts re drug paraphernalia. (a) No person shall use or possess with intent to use drug paraphernalia, as defined in subdivision (20) of section 21a-240, to plant, propagate, cultivate, grow, harvest, manufacture, compound, convert, produce, process, prepare, test, analyze, pack, repack, store, contain or conceal, or to inject, ingest, inhale or otherwise introduce into the human body, any controlled substance as defined in subdivision (9) of section 21a-240. Any person who violates any provision of this subsection shall be guilty of a class C misdemeanor.

(b) No person shall deliver, possess with intent to deliver or manufacture with intent to deliver drug paraphernalia knowing, or under circumstances where one reasonably should know, that it will be used to plant, propagate, cultivate, grow, harvest, manufacture, compound, convert, produce, process, prepare, test, analyze, pack, repack, store, contain or conceal, or to inject, ingest, inhale or otherwise introduce into the human body, any controlled substance. Any person who violates any provision of this subsection shall be guilty of a class A misdemeanor.

(c) Any person who violates subsection (a) or (b) of this section in or on, or within one thousand feet of, the real property comprising a public or private elementary or secondary school and who is not enrolled as a student in such school shall be imprisoned for a term of one year which shall not be suspended and shall be in addition and consecutive to any term of imprisonment imposed for violation of subsection (a) or (b) of this section.

(d) The provisions of subsections (a) and (b) of this section shall not apply to the possession or delivery of needles and syringes as part of the demonstration needle and syringe exchange program established pursuant to section 19a-124.

Sec. 21a-268. (Formerly Sec. 19-473). Misrepresentation of substance as controlled substance. Exemption. (a) Any person who knowingly delivers or attempts to deliver a

noncontrolled substance (1) upon the express representation that such substance is a controlled substance or (2) under circumstances which would lead a reasonable person to believe that such substance is a controlled substance, shall be guilty of a class D felony.

(b) The provisions of subsection (a) of this section shall not apply to any transaction in the ordinary course of business by any licensed practitioner or licensed pharmacist.

Sec. 21a-269. (Formerly Sec. 19-474). Burden of proof of exception, excuse, proviso or exemption. In any complaint, information or indictment, and in any action or proceeding brought for the enforcement of any provision of this part, it shall not be necessary to negative any exception, excuse, proviso or exemption contained in said section, and the burden of proof of any such exception, excuse, proviso or exemption shall be upon the defendant.

Sec. 21a-270. (Formerly Sec. 19-474a). Drug paraphernalia: Factors to be considered by court or other authority in determination. In determining whether any object or material listed in subdivision (20) of section 21a-240 shall be deemed "drug paraphernalia", a court or other authority shall, in addition to all other logically relevant factors, consider the following:

(1) Statements by an owner or by anyone in control of the object concerning its use;

(2) The proximity of the object to any controlled substances;

(3) The existence of any residue of controlled substances on the object;

(4) Evidence of the intent of an owner, or of anyone in control of the object, to deliver it to persons whom he knows, or should reasonably know, intend to use the object to facilitate a violation of this section, subdivision (20) of section 21a-240, and sections 21a-263, 21a-267 and 21a-271;

(5) Instructions, oral or written, provided with the object concerning its use with a controlled substance;

(6) Descriptive materials accompanying the object which explain or depict its use with a controlled substance;

(7) National and local advertising concerning its use;

(8) The manner in which the object is displayed for sale;

(9) Whether the owner, or anyone in control of the object, is a legitimate supplier of like or related items to the community, such as a licensed distributor or dealer of tobacco products;

(10) Evidence of the ratio of sales of the object to the total sales of the business enterprise;

(11) The existence and scope of legitimate uses for the object in the community;

(12) Expert testimony concerning its use.

Sec. 21a-271. (Formerly Sec. 19-474b). Severability of provisions concerning drug paraphernalia. If any section, part, clause or phrase in subdivision (20) of section 21a-240, section 21a-263, 21a-267, 21a-270 or this section, is for any reason held to be invalid or unconstitutional, sections, parts, clauses and phrases in said sections not held to be invalid or unconstitutional shall not be affected and shall remain in full force and effect.

Sec. 21a-272. (Formerly Sec. 19-475). Preparations which may be sold and dispensed. Exceptions. (a) The following preparations may be sold at retail in pharmacies and dispensed by hospitals, dentists, veterinarians and physicians without a prescription or written order, in quantities of not more than the amounts stated to any one person, or for the use of any one person or animal within forty-eight consecutive hours: (1) Four fluid ounces of Stokes expectorant, (2) four fluid ounces of Brown mixture, (3) eight fluid ounces of any preparation which contains camphorated tincture of opium or the opium equivalent not to exceed 16.2 mg. of

opium in one fluid ounce and from which the camphorated tincture of opium or the opium equivalent cannot be easily extracted.

(b) The exceptions authorized by this section shall be subject to the following conditions: (1) That the medicinal preparation administered, dispensed or sold shall contain, in addition to the morphine-type substance in it some drug or drugs conferring upon it medicinal qualities other than those possessed by the morphine-type substance alone; and (2) that such preparation shall be administered, dispensed and sold in good faith as a medicine and not for the purpose of evading the provisions of this part; and (3) that the purchaser of such preparations shall not purchase or attempt to obtain such preparations for the purpose of sustaining or satisfying a dependency upon controlled drugs; provided no vendor shall be deemed to have violated this subdivision unless he knew or should have known of such improper purpose; and (4) that the seller keep a schedule V record, as required by the commissioner of consumer protection, of the full name and address of the person purchasing the medicinal preparation, in the handwriting of the purchaser, the name and quantity of the preparation sold and the time and date of sale; and (5) that whenever a pharmacist sells or dispenses any schedule V substance which, under the provisions of this section, is excepted from prescriptions or written orders, the pharmacist shall securely affix to each package in which such drug is contained a label showing the name and address of the pharmacy. No person shall alter, deface or remove any label so affixed and no person shall have under his control or in his possession any such drug if not so labeled; and (6) that no provisions of this section shall be construed to permit the purchase, within any forty-eight hour period by any one person or for use of any one person or animal of more than one excepted schedule V preparation specified in subsection (a) or in more than the maximum amounts allowed under subsection (a) except as authorized by other provisions of this part.

(c) (1) The commissioner of consumer protection may, by regulation, exempt from the application of said sections to such extent as he determines to be consistent with the public welfare, pharmaceutical preparations containing schedule V substances found by said commissioner, after due notice and opportunity for hearing: (A) To possess no liability for drug abuse and dependency sufficient to warrant imposition of all of the requirements of said sections, and (B) not to permit recovery of a controlled substance having such liability for drug abuse and dependence with such relative technical simplicity and degree of yield as to create a risk of improper use. (2) In exercising the authority granted in subdivision (1) the commissioner of consumer protection, by regulation pursuant to section 21a-243 and without special findings, may grant exempt status to such pharmaceutical preparations as are determined to be exempt under the Federal Controlled Substances Act and regulations and permit the administering, dispensing or selling of such preparations under the same conditions as permitted by the federal regulations dealing therewith.

(d) After due notice and hearing, the commissioner of consumer protection may determine that a pharmaceutical preparation exempted from the oral or written prescription requirement under the provisions of this section does possess a potential for drug abuse and dependence and may, by regulation pursuant to section 21a-243, withdraw the prior exemption. Such determination shall be final, and, after the expiration of a period of six months from the date of issuance of the regulation, the exempt status shall cease to apply to the particular pharmaceutical preparation.

Sec. 21a-273. (Formerly Sec. 19-476). Substances exempt under federal law. (a) No prescription or written order shall be required for those controlled substances and preparations which are permitted by federal food and drug laws to be sold or dispensed without a prescription or written order to the extent that the person selling or dispensing such controlled substances and preparations is authorized by licensure of the state of Connecticut to so sell or dispense.

(b) If, after due notice and hearing, the commissioner of consumer protection determines that any pharmaceutical preparation exempted from the oral or written prescription

requirement under the provisions of subsection (a) of this section does possess a degree of liability for drug abuse or dependence that, in his opinion is likely to result in abuse, he shall, by regulation pursuant to section 21a-243, so state. The determination shall be final and, after the expiration of a period of six months from the date of publication of the regulation, the exempt status shall cease to apply to the particular pharmaceutical preparation.

Sec. 21a-274. (Formerly Sec. 19-477). Cooperation in enforcement of law. (a) The commissioners of health services and consumer protection and their authorized agents, police officers within their respective jurisdictions and all state's attorneys and prosecuting attorneys shall cooperate with each other and with other agencies charged with the enforcement of the laws of the United States, of this state and all other jurisdictions relative to controlled substances.

(b) Notwithstanding the provisions of section 21a-265 and chapter 55 said commissioners and their authorized agents may, in carrying out their duties under subsection (a), (1) exchange information relating to the issuance, suspension or revocation of a license issued by their respective agencies, or (2) exchange investigative information relating to violations of this chapter with each other, with state's attorneys and with other agencies charged with the enforcement of the laws of the United States, and of this state and all other jurisdictions relative to controlled substances.

Sec. 21a-274a. Drug enforcement grant program. There is established a drug enforcement grant program which shall be administered by the office of policy and management. Grants may be made to municipalities, the department of public safety, and the state-wide narcotics task force and the division of criminal justice for the purpose of enforcing federal and state laws concerning controlled substances, undertaking crime prevention activities related to the enforcement of such laws, substance abuse prevention education, or training related to such enforcement or education activities. The secretary of the office of policy and management shall adopt regulations in accordance with chapter 54 for the administration of this section, including the establishment of priorities, program categories, eligibility requirements, funding limitations and the application process.

Sec. 21a-275. (Formerly Sec. 19-478). Revocation or suspension of licenses by commissioner. (a) If the commissioner of consumer protection has reasonable cause to believe that a person licensed by him under section 21a-246, or any licensed practitioner, is violating or has violated any provision of sections 21a-243 to 21a-282, inclusive, relative to controlled substances, he may hold a hearing as to such violation upon reasonable notice and give opportunity to be heard to such licensee or practitioner.

(b) The commissioner may subpoena witnesses and papers on his own behalf and, if requested by the practitioner or licensee, may subpoena witnesses and papers in his behalf, may administer oaths, may compel the testimony of witnesses, may examine witnesses and may issue commissions to take testimony and testimony so taken and sworn to shall be admissible at such hearing. At such hearing the practitioner or licensee shall be entitled to representation by counsel.

(c) If the commissioner after a hearing finds that a person is violating or has violated any provision of sections 21a-243 to 21a-282, inclusive, he may revoke or suspend any license issued by him and forward his findings and the record upon which they are based to any other authority licensing such person with a recommendation that disciplinary action be taken.

Sec. 21a-276. (Formerly Sec. 19-479). Discretion of commissioner to issue warning. Nothing in sections 20-50, 20-164, as amended by section 7 of Public Act 95-264, 20-179, as amended by section 8 of Public Act 95-264, subdivision (3) of section 21a-92, subsection (e) of section 21a-115, sections 21a-240, 21a-243 to 21a-279, inclusive, and 21a-283, shall be construed

as requiring the commissioner of consumer protection to institute criminal or administrative action pursuant to said sections for violations thereof. In lieu of instituting criminal or administrative action pursuant to said sections, said commissioner may protect the public interest by serving suitable written notice or warning to the offending party or parties.

Sec. 21a-277. (Formerly Sec. 19-480). Penalty for illegal manufacture, distribution, sale, prescription, dispensing. (a) Any person who manufactures, distributes, sells, prescribes, dispenses, compounds, transports with the intent to sell or dispense, possesses with the intent to sell or dispense, offers, gives or administers to another person any controlled substance which is a hallucinogenic substance other than marihuana, or a narcotic substance, except as authorized in this chapter, for a first offense, shall be imprisoned not more than fifteen years and may be fined not more than fifty thousand dollars or be both fined and imprisoned; and for a second offense shall be imprisoned not more than thirty years and may be fined not more than one hundred thousand dollars, or be both fined and imprisoned; and for each subsequent offense, shall be imprisoned not more than thirty years and may be fined not more than two hundred fifty thousand dollars, or be both fined and imprisoned.

(b) Any person who manufactures, distributes, sells, prescribes, dispenses, compounds, transports with intent to sell or dispense, possesses with intent to sell or dispense, offers, gives or administers to another person any controlled substance, except a narcotic substance, or a hallucinogenic substance other than marihuana, except as authorized in this chapter, may, for the first offense, be fined not more than twenty-five thousand dollars or be imprisoned not more than seven years or be both fined and imprisoned; and, for each subsequent offense, may be fined not more than one hundred thousand dollars or be imprisoned not more than fifteen years, or be both fined and imprisoned.

(c) No person shall knowingly possess drug paraphernalia in a drug factory situation as defined by subdivision (20) of section 21a-240 for the unlawful mixing, compounding or otherwise preparing any controlled substance for purposes of violation of this chapter.

(d) As an alternative to the sentences specified in subsections (a) and (b) of this section, the court may sentence the person to the custody of the commissioner of correction for an indeterminate term not to exceed three years or the maximum term specified for the offense, whichever is the lesser, and, at any time within such indeterminate term and without regard to any other provision of law regarding minimum term of confinement, the commissioner of correction may release the convicted person so sentenced subject to such conditions as he may impose including, but not limited to, supervision by suitable authority. At any time during such indeterminate term, the commissioner of correction may revoke any such conditional release in his discretion for violation of the conditions imposed and return the convicted person to a correctional institution.

Sec. 21a-278. (Formerly Sec. 19-480a). Penalty for illegal manufacture, distribution, sale, prescription or administration by non-drug-dependent person. (a) Any person who manufactures, distributes, sells, prescribes, dispenses, compounds, transports with the intent to sell or dispense, possesses with the intent to sell or dispense, offers, gives or administers to another person one or more preparations, compounds, mixtures or substances containing an aggregate weight of one ounce or more of heroin, methadone or cocaine or an aggregate weight of one-half gram or more of cocaine in a free-base form or a substance containing five milligrams or more of lysergic acid diethylamide, except as authorized in this chapter, and who is not, at the time of such action, a drug-dependent person, shall be imprisoned for a minimum term of not less than five years nor more than twenty years; and, a maximum term of life imprisonment. The execution of the mandatory minimum sentence imposed by the provisions of this subsection shall not be suspended except the court may suspend the execution of such mandatory minimum

sentence if at the time of the commission of the offense (1) such person was under the age of eighteen years or, (2) such person's mental capacity was significantly impaired but not so impaired as to constitute a defense to prosecution.

(b) Any person who manufactures, distributes, sells, prescribes, dispenses, compounds, transports with the intent to sell or dispense, possesses with the intent to sell or dispense, offers, gives or administers to another person any narcotic substance, hallucinogenic substance other than marihuana, amphetamine-type substance, or one kilogram or more of a cannabis-type substance except as authorized in this chapter, and who is not at the time of such action a drug-dependent person, for a first offense shall be imprisoned not less than five years nor more than twenty years; and for each subsequent offense shall be imprisoned not less than ten years nor more than twenty-five years. The execution of the mandatory minimum sentence imposed by the provisions of this subsection shall not be suspended except the court may suspend the execution of such mandatory minimum sentence if at the time of the commission of the offense (1) such person was under the age of eighteen years or, (2) such person's mental capacity was significantly impaired but not so impaired as to constitute a defense to prosecution.

Sec. 21a-278a. Penalty for illegal manufacture, distribution, sale, prescription or administration involving minors. (a) Any person eighteen years of age or older who violates section 21a-277 or 21a-278, and who is not, at the time of such action, a drug-dependent person, by distributing, selling, prescribing, dispensing, offering, giving or administering any controlled substance to another person who is under eighteen years of age and is at least two years younger than such person who is in violation of section 21a-277 or 21a-278, shall be imprisoned for a term of two years, which shall not be suspended and shall be in addition and consecutive to any term of imprisonment imposed for violation of section 21a-277 or 21a-278.

(b) Any person who violates section 21a-277 or 21a-278 by manufacturing, distributing, selling, prescribing, dispensing, compounding, transporting with the intent to sell or dispense, possessing with the intent to sell or dispense, offering, giving or administering to another person any controlled substance in or on, or within one thousand five hundred feet of, the real property comprising a public or private elementary or secondary school, a public housing project or a licensed child day care center, as defined in section 19a-77, that is identified as a child day care center by a sign posted in a conspicuous place shall be imprisoned for a term of three years, which shall not be suspended and shall be in addition and consecutive to any term of imprisonment imposed for violation of section 21a-277 or 21a-278. To constitute a violation of this subsection, an act of transporting or possessing a controlled substance shall be with intent to sell or dispense in or on, or within one thousand feet of, the real property comprising a public or private elementary or secondary school, a public housing project or a licensed child day care center, as defined in section 19a-77, that is identified as a child day care center by a sign posted in a conspicuous place. For the purposes of this subsection "public housing project" means dwelling accommodations operated as a state or federally subsidized multifamily housing project by a housing authority, nonprofit corporation or municipal developer, as defined in section 8-39, pursuant to chapter 128 or by the Connecticut Housing Authority pursuant to chapter 129.

(c) Any person who employs, hires, uses, persuades, induces, entices or coerces a person under eighteen years of age to violate section 21a-277 or 21a-278 shall be imprisoned for a term of three years, which shall not be suspended and shall be in addition and consecutive to any term of imprisonment imposed for violation of section 21a-277 or 21a-278.

Sec. 21a-279. (Formerly Sec. 19-481). Penalty for illegal possession. Substitution of medical treatment for criminal sanctions. (a) Any person who possesses or has under his

control any quantity of any narcotic substance, except as authorized in this chapter, for a first offense, may be imprisoned not more than seven years or be fined not more than fifty thousand dollars, or be both fined and imprisoned; and for a second offense, may be imprisoned not more than fifteen years or be fined not more than one hundred thousand dollars, or be both fined and imprisoned; and for any subsequent offense, may be imprisoned not more than twenty-five years or be fined not more than two hundred fifty thousand dollars, or be both fined and imprisoned.

(b) Any person who possesses or has under his control any quantity of a hallucinogenic substance other than marihuana or four ounces or more of a cannabis-type substance, except as authorized in this chapter, for a first offense, may be imprisoned not more than five years or be fined not more than two thousand dollars or be both fined and imprisoned, and for a subsequent offense may be imprisoned not more than ten years or be fined not more than five thousand dollars or be both fined and imprisoned.

(c) Any person who possesses or has under his control any quantity of any controlled substance other than a narcotic substance, or a hallucinogenic substance other than marihuana or who possesses or has under his control less than four ounces of a cannabis-type substance, except as authorized in this chapter, for a first offense, may be fined not more than one thousand dollars or be imprisoned not more than one year, or be both fined and imprisoned; and for a subsequent offense, may be fined not more than three thousand dollars or be imprisoned not more than five years, or be both fined and imprisoned.

(d) Any person who violates subsection (a), (b) or (c) of this section in or on, or within one thousand five hundred feet of, the real property comprising a public or private elementary or secondary school and who is not enrolled as a student in such school or a licensed child day care center, as defined in section 19a-77, that is identified as a child day care center by a sign posted in a conspicuous place shall be imprisoned for a term of two years, which shall not be suspended and shall be in addition and consecutive to any term of imprisonment imposed for violation of subsection (a), (b) or (c) of this section.

(e) As an alternative to the sentences specified in subsections (a) and (b) and specified for a subsequent offense under subsection (c) of this section, the court may sentence the person to the custody of the commissioner of correction for an indeterminate term not to exceed three years or the maximum term specified for the offense, whichever is the lesser, and at any time within such indeterminate term and without regard to any other provision of law regarding minimum term of confinement, the commissioner of correction may release the convicted person so sentenced subject to such conditions as he may impose including, but not limited to, supervision by suitable authority. At any time during such indeterminate term, the commissioner of correction may revoke any such conditional release in his discretion for violation of the conditions imposed and return the convicted person to a correctional institution.

(f) To the extent that it is possible, medical treatment rather than criminal sanctions shall be afforded individuals who breathe, inhale, sniff or drink the volatile substances defined in subdivision (49) of section 21a-240.

Sec. 21a-280. (Formerly Sec. 19-481a). Breathing of anesthesia not violation. The breathing, inhalation, sniffing or drinking of anesthesia for medical or dental purposes under the direction of a physician or dentist, acting in the course of his professional practice, is determined to be a licit purpose and not in contravention of the provisions of this chapter.

Sec. 21a-281. (Formerly Sec. 19-481b). Presumption of psychological dependence on volatile substances. One who is found to have inhaled or to be under the influence of one or more of the volatile substances enumerated in subdivision (49) of section 21a-240 shall be presumed to be psychologically dependent upon such volatile substance or substances.

Sec. 21a-282. (Formerly Sec. 19-482). No prosecution where federal action has been taken. No person shall be prosecuted for a violation of any provision of sections 21a-243 to 21a-282, inclusive, if such person has been acquitted or convicted under the Federal Controlled Substances Act or under the federal food and drug laws for the same act or omission which, it is alleged, constitutes a violation of said sections.

Sec. 21a-283. (Formerly Sec. 19-483). Analytical tests for presence of controlled drugs or alcohol. Standards and procedures. Convictions constituting prior offense. Imposition of cost when analysis performed. (a) The chief toxicologist of the department of health services shall have primary responsibility for analysis of materials believed to contain controlled drugs, or of blood or urine believed to contain alcohol, for purposes of criminal prosecutions pursuant to this chapter; provided nothing herein shall be construed to preclude the use for such analyses of the services of other qualified toxicologists, pathologists and chemists, whether employed by the state or a municipality or a private facility or engaged in private practice, if such toxicologists, pathologists and chemists are engaged in operation of or employed by laboratories licensed by the commissioner of health services or the commissioner of consumer protection pursuant to section 21a-246. A laboratory of the United States Bureau of Narcotics is not required to be licensed under this section if it is approved by the chief toxicologist.

(b) The chief toxicologist shall establish the standards for analytical tests to be conducted with respect to controlled drugs, or with respect to body fluids believed to contain alcohol, by qualified professional toxicologists and chemists operating at his direction and shall have the general responsibility for supervising such analytical personnel in the performance of such tests. The original report of an analysis made by such analytical personnel of the department of health services or by a qualified toxicologist, pathologist or chemist of a laboratory of the United States Bureau of Narcotics shall be signed and dated by the analyst actually conducting the tests and shall state the nature of the analytical tests or procedures, the identification and number of samples tested and the results of the analytical tests. A copy of such report certified by the analyst shall be received in any court of this state as competent evidence of the matters and facts therein contained at any hearing in probable cause, pretrial hearing or trial. If such copy is to be offered in evidence at a trial, the attorney for the state shall send a copy thereof, by certified mail, to the attorney of the defendant who has filed an appearance of record or, if there is no such attorney, to the defendant if such defendant has filed an appearance pro se, and such attorney or defendant, as the case may be, shall, within five days of the receipt of such copy, notify the attorney for the state, in writing, if he intends to contest the introduction of such certified copy. No such trial shall commence until the expiration of such five-day period and, if such intention to contest has been filed, the usual rules of evidence shall obtain at such trial.

(c) In the case of any person charged with a violation of any provision of sections 21a-243 to 21a-279, inclusive, who has been previously convicted of a violation of the laws of the United States or of any other state, territory or the District of Columbia, relating to controlled drugs, such previous conviction shall, for the purpose of sections 21a-277 and 21a-279, be deemed a prior offense.

(d) In addition to any fine, fee or cost that may be imposed pursuant to any provision of the general statutes, the court shall impose a cost of fifty dollars upon any person convicted of a violation of this chapter if an analysis of a controlled substance in relation to the conviction was performed by or at the direction of the chief toxicologist of the department of health services. Any cost imposed under this subsection shall be credited to the appropriation for the department of health services and shall not be diverted for any other purpose than the provision of funds for the chief toxicologist.

CHAPTER 420c

CONTROLLED SUBSTANCE REGISTRATION

Sec. 21a-316. "Practitioner" defined. As used in this chapter, "practitioner" means: (1) A physician, dentist, veterinarian, podiatrist, osteopath, optometrist, physician assistant licensed pursuant to section 20-12b, as amended, advanced practice registered nurse as defined in subsection (b) of section 20-87a, nurse-midwife, scientific investigator or other person licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance in the course of professional practice or research in this state; (2) a hospital or other institution licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance in the course of professional practice or research in this state.

Sec. 21a-317. Registration required. Every practitioner who distributes, administers or dispenses any controlled substance or who proposes to engage in distributing, prescribing administering or dispensing any controlled substance within this state shall obtain a certificate of registration issued by the commissioner of consumer protection in accordance with the provisions of this chapter.

Sec. 21a-318. Application form. Fee. An application for registration pursuant to this chapter shall be made upon a form provided by the commissioner of consumer protection and shall be accompanied by a fee of ten dollars for annual registration, except that a practitioner who obtains such registration pursuant to the practitioner's employment with a municipality, this state or the federal government shall not be required to pay the fee.

Sec. 21a-319. Professional or institutional approval to precede registration. No certificate of registration shall be issued unless or until the applicant has furnished proof satisfactory to the commissioner of consumer protection that he or she is licensed or duly authorized to practice his or profession by the appropriate state licensing board, commission or registration agency; or, in the case of a hospital or other institution, by the appropriate state agency having jurisdiction over the licensure, registration or approval of such establishment.

Sec. 21a-320. Public interest standard for registration. The commissioner shall register an applicant unless he or she determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the commissioner shall consider the following factors:

(1) Maintenance of effective controls against diversion of controlled substances into other than duly authorized legitimate medical, scientific, or commercial channels;

(2) Compliance with all applicable state and federal laws and regulations concerning controlled substances;

(3) Any conviction of the applicant under any state or federal law relating to controlled substances;

(4) furnishing by the applicant of false or fraudulent information or material in any application filed under this chapter;

(5) Expiration, suspension, revocation, surrender or denial of the practitioner's federal controlled substance registration;

(6) prescribing, distributing, administering or dispensing of controlled substances in schedules other than those specified in the practitioner's state or federal registration.

Sec. 21a-321. Renewal of registration. Fee. Registration may be renewed by application to the commissioner of consumer protection. Renewal applications shall be in such form as the commissioner shall prescribe and shall be accompanied by an annual fee of ten dollars. A separate fee shall be required for each separate place of business or professional practice where the practitioner stores, distributes or dispenses controlled substances.

Sec. 21a-322. Grounds for suspension, revocation or refusal to renew. The commissioner may suspend, revoke or refuse to renew registration for sufficient cause. Any of the following shall be sufficient cause for suspension, revocation or refusal to renew: (1) The furnishing of false or fraudulent information in any application filed under this chapter; (2) conviction of a felony under any state or federal law relating to any controlled substance; (3) failure to maintain effective controls against diversion of controlled substances into other than duly authorized legitimate medical, scientific, or commercial channels; (4) the suspension, revocation, expiration or surrender of the practitioner's federal controlled substance registration; (5) prescribing, distributing, administering or dispensing a controlled substance in schedules other than those specified in the practitioner's state or federal registration; (6) the restriction, suspension, revocation or limitation of a professional license or certificate as a result of a proceeding pursuant to the general statutes; (7) abuse or excessive use of drugs; (8) possession, use, prescription for use or distribution of controlled substances or legend drugs, except for therapeutic or other proper medical or scientific purpose; and (9) a practitioner's failure to account for disposition of controlled substances as determined by an audit of the receipt and disposition records of said practitioner.

Sec. 21a-323. Hearing re refusal to renew registration or re denial, suspension or revocation of registration. Before denying, suspending revoking or refusing to renew a registration, the commissioner shall afford the applicant an opportunity for hearing in accordance with the provisions of chapter 54. Notice of such hearing shall be given by certified mail. The commissioner may subpoena witnesses and require the production of records, papers and documents pertinent to such hearing.

Sec. 21a-324. Voluntary surrender of certificate; effect upon registration. A practitioner may at any time voluntarily surrender his or her state controlled substance certificate of registration for any or all schedules of controlled substances for any of the following reasons: (1) As an indication of his or her good faith in desiring to remedy any incorrect or unlawful practices or (2) as a voluntary act arising out of his or her desire to terminate prescribing or handling of controlled substances in any or all schedules. Any such voluntary surrender shall constitute authority for the commissioner of consumer protection or his or her authorized agent to terminate and revoke any state controlled substance registration without a hearing or any other proceeding.

Sec. 21a-325. Disposal of controlled substances upon surrender of registration. Upon the surrender of a controlled substance certificate of registration for any or all schedules of controlled substances, as defined in section 21a-243, the registrant shall dispose of stocks of controlled substances as provided in regulations adopted under section 21a-262 or by the following procedure for disposition of controlled substances as outlined in section 1307.21 of the Code of Federal Regulations or any successor regulation.

Sec. 21a-326. Regulations. The commissioner of consumer protection may adopt such regulations as may be necessary to administer and enforce the provisions of this chapter.

Sec. 21a-327. Pharmacies, pharmacists and nurses exempt from chapter. Nothing in this chapter shall be construed to include pharmacies or pharmacists licensed under sections 1 to

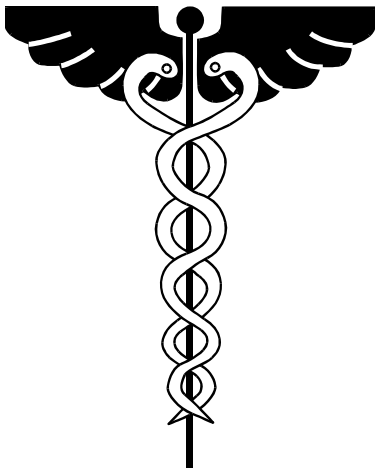
44, inclusive, of Public Act 95-364 or nurses licensed under chapter 378 who are not advanced practice registered nurses.

Sec. 21a-328. Penalty for failure to register. Upon the failure of a practitioner, as defined in section 21a-316, to comply with the provisions of this chapter the attorney general at the request of the commissioner of consumer protection is authorized to apply in the name of the state of Connecticut to the superior court for an order temporarily or permanently restraining and enjoining any practitioner from distributing, administering, dispensing or prescribing any controlled substance.

Secs. 21a-329 to 21a-334. Reserved for future use.

S E C T I O N II

Connecticut Public Acts



Substitute Senate Bill No. 1115

Public Act No. 05-41

AN ACT CONCERNING THE TRAINING OF PHARMACISTS.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. Subsection (a) of section 20-600 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

(a) Except as provided in subsections (b), (c), (f) and (g) of this section, the commission shall not authorize the department to renew a license to practice pharmacy as a pharmacist unless the pharmacist applying for the renewal submits a statement signed under the penalty of false statement that the pharmacist has satisfactorily completed not less than fifteen contact hours of accredited continuing professional education in the previous calendar year immediately preceding expiration of the license. Not less than five contact hours of the annual continuing education requirement shall be earned by attendance at a live presentation of an accredited continuing professional education program. At least one of the **[**five**]** fifteen contact hours **[**earned by attendance at a live presentation**]** shall be on the subject matter of pharmacy law or drug law.

Effective from passage

(For reference purposes this Public Act has been unofficially codified in section 20-600 of this law book).

Substitute Senate Bill No. 945

Public Act No. 05-73

AN ACT CONCERNING THE PRACTICE OF PHARMACY.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. Section 20-581 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

Any person who violates any provision of sections 20-570 to **[**20-630**]** 20-631, inclusive, and section 20-635 for the violation of which no other penalty has been provided shall be fined not more than five thousand dollars or imprisoned not more than five years or both. For purposes of this section, each instance of patient contact or consultation that is in violation of any provision of sections 20-570 to **[**20-630**]** 20-631, inclusive, and section 20-635 shall be a separate offense. Failure to renew in a timely manner any license issued under said sections is not a violation for purposes of this section.

Sec. 2. Section 21a-249 of the general statutes is amended by adding subsection (m) as follows (*Effective from passage*):

(NEW) (m) A practitioner authorized to prescribe controlled substances shall not prescribe anabolic steroids for the sole purpose of enhancing a patient's athletic ability or performance.

Sec. 3. (NEW) (*Effective from passage*) In the absence of a documented patient evaluation that includes a physical examination, any request for a controlled substance issued solely on the results of answers to an electronic questionnaire shall be considered to be issued outside the context of a valid practitioner-patient relationship and not be a valid prescription. The Commissioner of Consumer Protection may adopt regulations, in accordance with chapter 54 of the general statutes, concerning such requests for controlled substances. For the purposes of this section, "electronic questionnaire" means any form in an electronic format that may require personal, financial or medical information from a consumer or patient.

Effective from passage

(For reference purposes, the above amendment has been unofficially added to Section 20-581 and Section 21a-249 of this law book)

Substitute House Bill No. 6557

Public Act No. 05-168

AN ACT CONCERNING ELECTRONIC PRESCRIPTIONS AND ELECTRONIC MEDICAL RECORDS.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. (NEW) (*Effective October 1, 2005*) Each health care provider licensed in this state with prescriptive authority may generate prescriptions in this state utilizing an electronic prescribing system. The Department of Consumer Protection may, within available appropriations, advise and assist health care providers in such utilization.

Sec. 2. Subsection (e) of section 1-283 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2005*):

(e) Except as otherwise provided in subsection (f) of section 1-277 and section 1 of this act, sections 1-266 to 1-286, inclusive, do not require a governmental agency in this state to use or permit the use of electronic records or electronic signatures.

Sec. 3. (NEW) (*Effective October 1, 2005*) A health care institution licensed by the Department of Public Health pursuant to chapter 368v of the general statutes may create, maintain or utilize medical records or a medical records system in electronic format, paper format or both, provided such records or system are designed to store

medical records or patient health information in a medium that is reproducible and secure.

Sec. 4. Section 19a-639a of the general statutes is amended by adding subsection (c) as follows (*Effective October 1, 2005*):

(NEW) (c) The Office of Health Care Access shall, in its discretion, exempt from certificate of need review pursuant to sections 19a-638 and 19a-639 any health care facility or institution that proposes to purchase or operate an electronic medical records system on or after October 1, 2005.

Effective October 1, 2005

(For reference purposes this Public Act has <u>not</u> been unofficially codified in this law book).

Substitute House Bill No. 6970

Public Act No. 05-217

AN ACT ESTABLISHING A COLLABORATIVE DRUG THERAPY MANAGEMENT AGREEMENT PILOT PROGRAM.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. Subsection (a) of section 20-631 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2005*):

(a) (1) One or more pharmacists licensed under this chapter who are determined eligible in accordance with subsection (c) of this section, and employed by a hospital may enter into a written protocol-based collaborative drug therapy management agreement with one or more physicians licensed under chapter 370 to manage the drug therapy of individual patients receiving inpatient services in a hospital licensed under chapter 368v, in accordance with subsections (b) to (d), inclusive, of this section and subject to the approval of the hospital. Each patient's collaborative drug therapy management shall be governed by a written protocol specific to that patient established by the treating physician in consultation with the pharmacist.

(2) One or more pharmacists licensed under this chapter who are determined eligible in accordance with subsection (c) of this section and employed by or under contract with a nursing home facility, as defined in section 19a-521, may enter into a written protocol-based collaborative drug therapy management agreement with one or more physicians licensed under chapter 370 to manage the drug therapy of individual patients receiving services in a nursing home facility, in accordance with subsections (b) to (d), inclusive, of this section and subject to the approval of the nursing home facility. Each patient's collaborative drug therapy management shall be governed by a written protocol specific to that patient established by the treating physician in consultation with the

pharmacist. Each such protocol shall be reviewed and approved by the active organized medical staff of the nursing home in accordance with the requirements of section 19-13-D8t(i) of the Public Health Code.

(3) One or more pharmacists licensed under this chapter who are determined eligible in accordance with subsection (c) of this section and employed by or under contract with a hospital licensed under chapter 368v may enter into a written protocol-based collaborative drug therapy management agreement with one or more physicians licensed under chapter 370 to manage the drug therapy of individual patients receiving outpatient hospital care or services for diabetes, asthma, hypertension, hyperlipidemia, osteoporosis, congestive heart failure or smoking cessation, including patients who qualify as targeted beneficiaries under the provisions of Section 1860D-4(c)(2)(A)(ii) of the federal Social Security Act, in accordance with subsections (b) to (d), inclusive, of this section and subject to the approval of the hospital. Each patient's collaborative drug therapy management shall be governed by a written protocol specific to that patient established by the treating physician in consultation with the pharmacist.

Sec. 2. (*Effective from passage*) Not later than January 1, 2006, the Commissioner of Consumer Protection, in consultation with the Commission of Pharmacy, shall establish and operate a two-year pilot program to allow not more than ten pharmacists licensed under chapter 400j of the general statutes who are determined eligible in accordance with subsection (c) of this section and employed by or under contract with a licensed community pharmacy, to enter into a written protocol-based collaborative drug therapy management agreement with one or more physicians licensed under chapter 370 of the general statutes, to manage the drug therapy of individual patients receiving drug therapy for diabetes, asthma, hypertension, hyperlipidemia, osteoporosis, congestive heart failure or smoking cessation, including patients who qualify as targeted beneficiaries under the provisions of Section 1860D-4(c)(2)(A)(ii) of the federal Social Security Act, in accordance with subsections (b) to (d), inclusive, of this section and subject to the approval of the licensed community pharmacy. Each patient's collaborative drug therapy management shall be governed by a written protocol specific to that patient established by the treating physician in consultation with the pharmacist.

(b) A collaborative drug therapy management agreement may authorize a pharmacist to implement, modify or discontinue a drug therapy that has been prescribed for a patient, order associated laboratory tests and administer drugs, all in accordance with a patient-specific written protocol. Each protocol developed, pursuant to the collaborative drug therapy management agreement, shall contain detailed direction concerning the actions that the pharmacist may perform for that patient. The protocol shall include, but need not be limited to, (1) the specific drug or drugs to be managed by the pharmacist, (2) the terms and conditions under which drug therapy may be implemented, modified or discontinued, (3) the conditions and events upon which the pharmacist is required to notify the physician, and (4) the laboratory tests that may be ordered. All activities performed by the pharmacist in conjunction with the protocol shall be documented in the patient's medical record. The pharmacist shall report to the physician through oral, written or electronic manner regarding the implementation, administration, modification or discontinuation of a drug therapy that has been prescribed for a patient

not later than twenty-four hours after such implementation, administration, modification or discontinuation. The collaborative drug therapy management agreement and protocols shall be available for inspection by the Departments of Public Health and Consumer Protection. A copy of the protocol shall be filed in the patient's medical record.

(c) In order to be selected for participation in the program, a pharmacist shall be responsible for demonstrating, in accordance with this subsection, the competence necessary for participation in each drug therapy management agreement into which such pharmacist may enter. The pharmacist's competency shall be determined by the Commission of Pharmacy using criteria based on the continuing education requirements of sections 20-599 and 20-600 of the general statutes.

(d) The Commissioner of Consumer Protection and the Commission of Pharmacy shall evaluate the pilot program established under this section and shall submit a report of the commissioner's findings and recommendations to the joint standing committees of the General Assembly having cognizance of matters relating to public health, human services and general law, not later than December 31, 2008, in accordance with the provisions of section 11-4a of the general statutes. Such report shall include an evaluation of the data collected with respect to improved medication management and cost savings, based on patient outcomes.

(e) Records or information collected or maintained pursuant to this section shall not be disclosed pursuant to subsection (a) of section 1-210 of the general statutes for a period of six months from the date such records or information were created or collected and shall not be subject to subpoena or discovery or introduced into evidence in any judicial or administrative proceeding except as otherwise specifically provided by law.

(f) For purposes of this section, "community pharmacy" means a pharmacy licensed under section 20-594 of the general statutes that stores and dispenses legend drugs, as defined by section 20-571 of the general statutes, and legend devices, as defined by said section 20-571, and from which related pharmaceutical care services are provided, primarily to noninstitutionalized patients living in a community setting.

Effective October 1, 2005

(For reference purposes sections of this Public Act has been unofficially codified in sections 20-631 of this law book).

Substitute House Bill No. 6791

Public Act No. 05-212

AN ACT IMPLEMENTING THE RECOMMENDATIONS OF THE LEGISLATIVE PROGRAM REVIEW AND INVESTIGATIONS COMMITTEE RELATIVE TO PHARMACY REGULATION.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. (NEW) (*Effective from passage*) Not later than January 1, 2006, the Department of Consumer Protection shall submit to the joint standing committee of the General Assembly having cognizance of matters relating to general law, in accordance with the provisions of section 11-4a of the general statutes, a report that summarizes the activities of the department related to the regulation of the Pharmacy Practice Act, the federal Food, Drug and Cosmetic Act and the state controlled substance act. Such report shall include, but not be limited to, information on the number and type of pharmacy inspections and investigations conducted by the Department of Consumer Protection concerning: (1) The number of investigations conducted, (2) the reason for each investigation, (3) the subject matter of each investigation, (4) the outcome of each investigation, (5) any action taken by any board of the Department of Public Health or the Commission of Pharmacy, (6) any action taken by the Commissioner of Consumer Protection on a practitioner's controlled substance registration, and (7) the timeline for such investigation beginning with the opening of such case investigation and ending with the final board or commission action. Such report shall be updated and resubmitted to the said joint standing committee on January 1, 2007, and on January 1, 2008.

Sec. 2. (NEW) (*Effective from passage*) Not later than January 1, 2006, in accordance with the provisions of section 11-4a of the general statutes, The University of Connecticut Health Center shall submit a report to the Legislative Program Review and Investigations Committee that identifies deficiencies in the administration of drugs in correctional facilities found within the previous calendar year. Such report shall be updated on January 1, 2007, and on January 1, 2008.

Sec. 3. Section 20-577 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

(a) The commissioner shall employ inspectors whose duty it shall be to inspect all pharmacies and other places in which drugs and devices are or may be dispensed or retailed, and to report any violations of sections 20-570 to 20-630, inclusive, or other laws relating to drugs and devices and violations of laws regarding pharmacy licenses, nonlegend drug permits, licenses of pharmacists and supervision of pharmacy interns and pharmacy technicians.

(b) The commissioner shall inspect correctional or juvenile training institutions and care-giving institutions throughout the state with respect to the handling of drugs, shall report violations of law and make recommendations for improvements in procedures to the authority responsible for the operation of the institution and shall take such other

steps as may be necessary to ensure proper and adequate storage, handling and administration of drugs in such institutions. The commissioner may also inspect dispensing outpatient facilities and institutional pharmacies and take such steps as the commissioner considers appropriate to correct deficiencies found in such facilities or institutional pharmacies with respect to their operation.

(c) The commissioner shall inspect each retail pharmacy not less than once every four years and shall develop a methodology to sample prescriptions dispensed by retail pharmacies for compliance with state laws concerning the dispensing of prescriptions. Such methodology shall be based on the number of prescriptions received by such retail pharmacies.

Sec. 4. Section 21a-262 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

(a) The Commissioner of Consumer Protection may receive, take into custody or destroy excess or undesired controlled substances and may in his discretion deliver, upon application, to any hospital, laboratory, incorporated college, scientific institution or any state or municipal agency or institution not operated for private gain, any controlled substances that have come into his custody by authority of this section. In the case of a care-giving or correctional or juvenile training institution having an institutional pharmacy, the Commissioner of Consumer Protection shall deliver such controlled substances only to the licensed pharmacist in charge of such pharmacy. The Commissioner of Consumer Protection may receive and take into custody excess or undesired controlled substances from pharmacists, manufacturers and wholesalers or any other registrant. Said commissioner shall keep a full and complete record of all substances received and of all substances disposed of, showing the exact kinds, quantities and forms of such substances, the persons from whom received and to whom delivered, by whose authority received, delivered and destroyed, and the dates of the receipt, disposal or destruction. Controlled substances and preparations shall at all times be properly safeguarded and securely kept. Minimum security and safeguard standards for the storage, manufacture, sale or distribution of all controlled substances shall be established by regulations adopted hereunder. Controlled substances seized or held as contraband or controlled substances, the title to which cannot be resolved, which controlled substances are not held by law enforcement agencies or court officials as evidence in criminal proceedings, shall be, upon the order of the court, destroyed by the seizing authority or delivered to the Commissioner of Consumer Protection as soon as possible upon resolution of the case or upon ascertaining the status of the unclaimed substance. The agent of the Commissioner of Consumer Protection shall issue a receipt for all such substance obtained. Any loss, destruction or theft of controlled substances shall be reported by a registrant within seventy-two hours to the Commissioner of Consumer Protection as follows: (1) Where, through breakage of the container or other accident, otherwise than in transit, controlled substances are lost or destroyed, the person having title thereto shall make a signed statement as to the kinds and quantities of controlled substances lost or destroyed and the circumstances involved, and immediately forward the statement to the Commissioner of Consumer Protection. A copy of such statement shall be retained by the registrant; (2) where controlled substances are lost by theft, or otherwise lost or destroyed in transit, the consignee shall,

immediately upon ascertainment of the occurrence, file with the Commissioner of Consumer Protection a signed statement of the facts, including a list of the controlled substances stolen, lost or destroyed and documentary evidence that the local authorities were notified. A copy of the statement shall be retained by the registrant. As used in this section, "care-giving institution", "correctional or juvenile training institution", "institutional pharmacy" and "pharmacist" shall have the same meaning as used in section 20-571.

(b) For each long-term care facility, two or more of the following persons may jointly dispose of excess stock of controlled substances: A nursing home administrator, a pharmacist consultant, a director of nursing services or an assistant director of nursing services. Such facility shall maintain documentation of any such destruction and disposal for a period of three years and such documentation shall be maintained in a separate log and on a form prescribed by the department.

(c) For each outpatient surgical facility, as defined in section 19a-493b, two or more of the following persons may jointly dispose of excess stock of controlled substances: An administrator, a clinical director or chief of staff, or a nursing supervisor. Such facility shall maintain documentation of any such destruction and disposal for a period of three years and such documentation shall be maintained in a separate log and on a form prescribed by the department.

Sec. 5. (NEW) (*Effective from passage*) Not less than once every three months, the Department of Consumer Protection shall compile a regulatory action report that contains information regarding: (1) Any disciplinary action taken by the department against any person with a controlled substance registration, and (2) any sanction by the Commission of Pharmacy against a pharmacy or pharmacist. Such report shall contain the reasons for any such action or sanction and shall be posted on the web site of the department.

Sec. 6. (NEW) (*Effective from passage*) (a) On and after October 1, 2005, any person licensed as a pharmacist under part II of chapter 400j of the general statutes may administer influenza vaccine to an adult, provided the administration is conducted pursuant to the order of a licensed health care provider and in accordance with the regulations established pursuant to subsection (b) of this section.

(b) Not later than September 1, 2005, the Commissioner of Consumer Protection, in consultation with the Commissioner of Public Health and the Commission of Pharmacy, shall adopt regulations, in accordance with chapter 54 of the general statutes, to implement the provisions of this section. Such regulations shall (1) require any pharmacist who administers influenza vaccine to an adult pursuant to this section to successfully complete an immunization training program for pharmacists; (2) define the basic requirements of such training program, which shall include training and instruction in pre-administration education and screening, vaccine storage and handling, subcutaneous and intramuscular injections, recordkeeping, vaccine safety, cardiopulmonary resuscitation, basic cardiac life support and adverse event reporting; (3) identify qualifying training programs, which are accredited by the National Centers for Disease Control Prevention, the Accreditation Council for Pharmacy Education or

other appropriate national accrediting body; and (4) establish a system of control and reporting.

(c) For purposes of this section, "adult" means an individual who has attained the age of eighteen years.

Effective from passage.

(For reference purposes sections of this Public Act has been unofficially codified in sections 20-577 and 21a-262 of this law book).

House Bill No. 5292

Public Act No. 05-233

AN ACT CONCERNING THE REQUIREMENT THAT PRESCRIPTIONS BE FILLED BY MAIL ORDER.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. (NEW) (*Effective July 1, 2005*) (a) No health insurance policy issued on an individual basis, whether issued by an insurance company, a hospital service corporation, a medical service corporation or a health care center, which provides coverage for prescription drugs may require any person covered under such policy to obtain prescription drugs from a mail order pharmacy as a condition of obtaining benefits for such drugs.

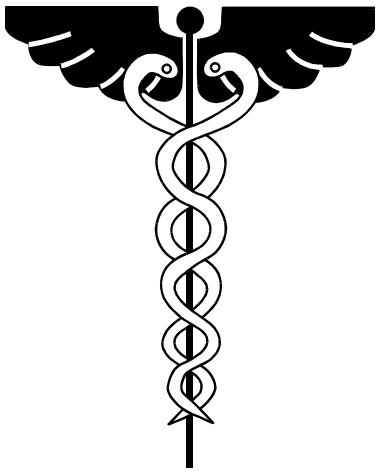
(b) The provisions of this section shall apply to any such policy delivered, issued for delivery, renewed, amended or continued in this state on or after July 1, 2005.

Effective July 1, 2005

(For reference purposes, the above amendment has <u>not</u> been added to this law book)

S E C T I O N III

Regulations of Connecticut State Agencies



Pharmacy Practice Regulations

The Practice of Pharmacy

Sec. 20-576-1. Definitions

For the purpose of sections 20-576-1 through 20-576-53 of the Regulations of Connecticut State Agencies, the following terms shall have the meanings indicated:

(a) "Commission" means the commission of Pharmacy;

(b) "Department" means the Department of Consumer Protection;

(c) "Legend drug" has the meaning given to this term by Section 20-571 of the General Statutes;

(d) "Prescribing practitioner" has the meaning given to this term by Section 20-571 of the General Statutes; and

(e) "Prescription department" means that area within a pharmacy where drugs are compounded and dispensed pursuant to the order of a prescribing practitioner

Sec. 20-576-2. Applications

(a) All applications for licenses or permits shall be made on forms furnished by the department. All such forms shall be signed by the applicant thereby indicating that all information contained in the application is true and accurate.

(b) Proper proof of all requirements for applications for admission to examinations and for applications for licenses and permits shall be provided to the department with each such application.

(c) Applications for licenses for which an examination is required shall be submitted to the department at least forty-five days prior to the date on which the examination is to be taken unless this is deemed by the commission to be unnecessary based upon the manner in which the exam is to be administered.

(d) Applications for new pharmacy licenses and applications for the relocation of a pharmacy shall be made at least fifteen days prior to the next scheduled meeting of the commission.

Sec. 20-576-3. Applications for pharmacist license

(a) An applicant for a license to practice pharmacy other than by reciprocity shall be required to take a four part examination consisting of the following:

(1) Part I. The North American Pharmacist Licensure Exam or such other examination as may be required by the commission and approved by the Commissioner of Consumer Protection;

(2) Part II. Contemporary Pharmacy Practice, including but not limited to, skills such as patient counseling, disease state management and compounding and dispensing of medication;

(3) Part III. Pharmaceutical jurisprudence; and

(4) Part IV. Pharmaceutical mathematics.

(b) The applicant must achieve a grade of not less than 75 in each designated part.

Sec. 20-576-4. Eligibility for examination

(a) An applicant who is a graduate of a school or college of pharmacy accredited by the American Council on Pharmaceutical Education and approved by the commission, and who has had at least fifteen hundred hours of the practical experience required of a pharmacy intern shall be eligible to take the required examination, except as provided in section 20-576-6 of the Regulations of Connecticut State Agencies.

(b) An applicant who is a graduate of a foreign college or school of pharmacy shall be eligible to take the required examination if the following requirements are met:

(1) Documentation of date and place of birth;

(2) Proof of having passed the Test of English as a Foreign Language with a minimum score of fifty-five (55) in each section and a total score of not less than five hundred fifty (550);

(3) Proof of having passed the Test of Spoken English with a minimum score of fifty-five (55);

(4) Proof of United States citizenship or a visa permitting employment in the United States;

(5) Proof of at least fifteen hundred hours of the practical experience required of a pharmacy intern as provided by section 20-576-8 of the Regulations of Connecticut State Agencies;

(6) Proof of passage of the Foreign Pharmacy Graduate Equivalency Examination; and

(7) Appearance before the commission for a personal interview prior to the commencement of the practical experience required of a pharmacy intern in subsection (b)(5) of this section, at which time such training requirement as well as the other criteria established in this subsection will be reviewed.

Sec. 20-576-5. Examination conduct

Any candidate committing a fraudulent or deceitful act related to the taking of the examination shall be prohibited from further examination for a minimum period of one year.

Sec. 20-576-6. Exception to intern requirements

If a candidate for the examination for licensure to practice pharmacy as a pharmacist in Connecticut as prescribed by section 20-590 of the General Statutes and section 20-576-3 of the Regulations of Connecticut State Agencies has not fulfilled the law as required by section 20-598 of the General Statutes, the candidate, upon completion of the examination, shall immediately register and fulfill the requirements of said section 20-598, or, submit to the commission evidence of the completion of a program as described in section 20-576-8(b) of the Regulations of Connecticut State Agencies.

Sec. 20-576-7. Reciprocity

A pharmacist who is licensed as such in any other state of the United States, the District of Columbia, the Commonwealth of Puerto Rico or any territory or insular possession subject to the jurisdiction of the United States, may be licensed to practice as such in this state provided:

(1) the qualifications necessary to secure such license in the state or jurisdiction in which the pharmacist is licensed were, at the time of first securing such license, at least equal to those required in this state at that time;

(2) the pharmacist is a graduate with a professional undergraduate degree from those schools of pharmacy that are accredited by the American Council on Pharmaceutical Education, or is a graduate with a professional undergraduate degree from a foreign college or school of pharmacy and has complied with the requirements of section 20-576-4(b) of the Regulations of Connecticut State Agencies;

(3) the pharmacist is a resident of the state of Connecticut at the time of making application to be licensed as a pharmacist or has indicated an intention to practice pharmacy within the state of Connecticut;

(4) the pharmacist has practiced the profession of pharmacy for at least one year in any other state or jurisdiction within the last five years at the time of application or has been licensed by examination in an other state or jurisdiction within the previous twelve months. In lieu of the practice requirement, the commission may accept, in its discretion,equiivalent experience as determined by the commission

(5) the pharmacy board or commission in the state or jurisdiction from which the pharmacist is reciprocating grants similar reciprocal privileges to pharmacists licensed in this state;

(6) the pharmacist passes that portion of the commission's licensure examination relating to pharmacy law; and

(7) the pharmacist appears before the commission for a personal interview in which the criteria established in this section will be reviewed.

Sec. 20-576-8. Registration of pharmacy interns

(a) As used in this section: "pharmacy intern" has the meaning given to this term by Section 20-571 of the General Statutes; "intern training pharmacy" means a Connecticut pharmacy or an institutional pharmacy approved by the commission, providing training for a pharmacy intern in contemporary pharmacy practice; and "pharmacy intern preceptor" means a Connecticut pharmacist supervising a pharmacy intern.

(b) The professional experience required by section 20-590 of the General Statutes shall consist of the satisfactory fulfillment of a series of objectives approved by the commission, completed during fifteen hundred clock hours as a registered pharmacy intern. No more than 40 clock hours may be obtained in any one week. The professional experience may be obtained by completing any combination of the following:

(1) work in a Connecticut pharmacy or an institutional pharmacy approved by the commission;

(2) an educational experiential program established and monitored by a school or college of pharmacy accredited by the American Council on Pharmaceutical Education and approved by the commission;

(3) an out of state practical experience program approved by the appropriate licensing agency in the state wherein the experience is attained; or

(4) an industrial, research or other professional experience program established by a school or college of pharmacy accredited by the American Council on Pharmaceutical Education and approved by the commission. Hours accumulated under this subdivision shall be limited to a maximum of 400 hours.

(c) The following requirements shall apply only to experience hours acquired by a pharmacy intern working in a Connecticut pharmacy or institutional pharmacy approved by the commission:

(1) No pharmacy intern preceptor shall supervise the training of more than one pharmacy intern at any one time;

(2) A pharmacy intern preceptor's statement supplied by the department shall be completed and signed by the preceptor and the intern, certifying that the stated hours and content of the professional experience are true;

(3) The pharmacy intern shall within five days of the event, notify the commission of any of the following changes in his internship training:

(A) the commencement of his internship training;

(B) a change in the place of supervision;

(C) a change of the pharmacy intern preceptor;

(D) a change in the hours of supervision; or

(E) cessation of supervision; and

(4) The department shall issue to each pharmacy intern, registering in accordance with section 20-598 of the General Statutes, an identification number and card except to those individuals obtaining internship training in an out of state practical experience program approved by the licensing agency in the state wherein the experience is attained.

Sec. 20-576-9. Authority of registered pharmacy intern

A registered pharmacy intern may compound and dispense drugs and devices and otherwise perform contemporary pharmacy services only when a pharmacist is physically present in the pharmacy or institutional pharmacy and personally supervising such compounding, dispensing or delivery of contemporary pharmacy services.

Sec. 20-576-10. Information to be reported

Every pharmacist who commences the practice of pharmacy or changes the pharmacist's place of employment within the state of Connecticut shall report to the department within five days the following information:

(1) the date of commencement of the practice of pharmacy;
(2) the name of the pharmacist's employer;
(3) the address of the practice location; and
(4) the type of practice.

Sec. 20-576-11. Change of name or address

Any pharmacist or registered pharmacy technician changing the pharmacist's or technician's name or home address shall notify the commission of such change within five days.

Sec. 20-576-12. Required pharmacy equipment and references

Every pharmacy and institutional pharmacy shall have proper pharmaceutical equipment and appropriate pharmaceutical reference materials to insure that prescriptions can be properly dispensed and that contemporary pharmacy services can be properly provided.

Sec. 20-576-13. Hours of operation of a pharmacy.

A pharmacy shall be open at least thirty-five hours per week, except as otherwise authorized in regulations concerning classes of pharmacies promulgated pursuant to Section 20-576(a)(2) of the General Statutes.

Sec. 20-576-14. Security of the prescription department during momentary absences of a pharmacist.

During times when the pharmacist leaves the prescription department, or leaves the area operated as the pharmacy in accordance with sections 20-576-15 and 20-576-16 of the Regulations of Connecticut State Agencies, for a few moments, measures shall be taken to insure that adequate security of the prescription department is provided and that entry by unauthorized personnel is prevented or immediately detected. The presence of a pharmacy intern or a pharmacy technician in the prescription department, or in the area operated as the pharmacy in accordance with section 20-576-15 and 20-576-16 of the Regulations of Connecticut State Agencies, during these times shall be considered to be providing adequate security. If no such personnel are available for this purpose, and the prescription department, or the area licensed as the pharmacy in accordance with sections 20-576-15 and 20-576-16 of the Regulations of Connecticut State Agencies, is not within the view of the pharmacist, a method shall be employed to physically or electronically secure the prescription department through the use of mechanisms such as a locked barrier or an alarm system that will prevent or immediately detect access to that area.

Sec. 20-576-15. Licensing as a pharmacy the entire premises of a business not primarily devoted to the operation of a pharmacy

The commission shall not be required to license as a pharmacy, the entire premises of a business that is not devoted primarily to the operation of a pharmacy. In determining whether to license the entire premises the commission shall consider, but shall not be limited to the following factors:

(1) the primary nature of the business and the type of products sold, especially the relationship of the products sold to the practice of pharmacy; and

(2) the percentage of the floor space of the business devoted to the sale of drugs, medical devices and other health related products.

Sec. 20-576-16. Physical construction and operation of pharmacies located in businesses not devoted primarily to the operation of a pharmacy

When a pharmacy is operated in any store, firm or other business not devoted primarily to the operation of a pharmacy, the following provisions shall be met:

(1) The area which is licensed as a pharmacy shall be completely separated from other business operations by partitions approved by the commission and the entire pharmacy shall be arranged or constructed to prevent the public from having unauthorized or illegal access to any drugs or medical devices;

(2) Such pharmacy shall be constructed so that it can be completely secured and locked to prevent unauthorized entry during times when the pharmacy is closed and the pharmacist is not present;

(3) The hours of operation of the pharmacy shall be conspicuously displayed at the main outside entrance of the business, store or firm;

(4) Access to the pharmacy by an authorized pharmacist shall be provided twenty-four hours daily;

(5) Exterior and interior signs exhibited by such business which use words such as "pharmacy," "drug store," "apothecary" or other words indicating that such place of business houses a pharmacy shall not be positioned in such a way, or be of such size, as to imply that the entire premises is a pharmacy;

(6) The portion of the premises occupied by a pharmacy may have a door admitting the public directly into said pharmacy from outside of the building, from a public way within a shopping mall or plaza or from a lobby which leads directly to the outside; and

(7) In a business, store or firm where there is no access providing direct access to the pharmacy in accordance with subdivision (6) of this section, the pharmacy shall be located in an area which is approved by the commission of Pharmacy and which provides for convenience and ease of access to patients.

Sec. 20-576-17. Closing of prescription department

(a) The pharmacist manager of a pharmacy may apply to the commission for permission to close the prescription department during specified hours. Prior to granting the applicant's request, the commission shall request that the Commissioner of Consumer Protection inspect the pharmacy for compliance with sections 20-576-17 through 20-576-19, inclusive, of the Regulations of Connecticut State Agencies. Upon confirmation from the Commissioner of Consumer Protection that the pharmacy is in compliance with those regulations, the commission shall grant such permission. A record of such application and its approval shall be maintained on file by the commission.

(b) After approval is granted pursuant to subsection (a) of this section, a pharmacy may reduce the hours the prescription department is open if:

(1) The pharmacist manager files notice of such reduction of hours with the Department of Consumer Protection at least thirty days prior to such change; and

(2) The pharmacy posts a conspicuous notice to the public at least thirty days prior to such reduction of hours.

(c) After approval is granted pursuant to subsection (a) of this section, a pharmacy may increase the hours the prescription department is open. The pharmacist

manager shall file notice of such increase of hours with the Department of Consumer Protection not later than five days after such change.
The prescription department of a pharmacy shall be open to provide pharmaceutical services not less than thirty-five hours per week.

Sec. 20-576-18. Procedures when prescription department closed

(a) During times that the prescription department is closed, it shall be securely locked and equipped with an alarm system. Such alarm shall be activated and operated separately from any other alarm system at the pharmacy, and shall be able to detect entrance to the prescription department at times when it is closed. Keys and access codes to the alarm system shall be controlled in such a manner so as to prevent access to the prescription department by other than authorized pharmacy personnel. Only a pharmacist shall have the authority to deactivate the alarm system.

(b) Original written prescriptions, prescription containers to be refilled or written requests for prescription refills may be left at the pharmacy at times when the prescription department is closed only if they are deposited directly into a drop box by a patient or his agent. Such box shall be a one-way container constructed in a manner which ensures that deposited items are not retrievable other than from inside the pharmacy by the pharmacist or his designee and only at times when the pharmacist is present in the pharmacy.

(c) Prescriptions which have been prepared for pickup, legend drugs, controlled substances, legend devices and products whose sale is limited to pharmacies or shall be carried out by or under the supervision of a pharmacist, shall be stored within the prescription department or in a separate locked storage area and no sales of such products shall take place when the prescription department is closed.

(d) When the prescription department is closed, deliveries from manufacturers, wholesalers or other drug distributors of legend drugs, controlled substances, legend devices and products whose sale is limited to pharmacies or shall be carried out by or under the supervision of a pharmacist, shall be stored in a secure locked area until such time that a pharmacist is present in the pharmacy and the orders can be processed under a pharmacist's supervision.

Sec. 20-576-18a Unscheduled closing of the prescription department or the pharmacy

(a)(1) A pharmacy that has received approval from the commission, in accordance with section 20-576-17 of the Regulations of Connecticut State Agencies, to close the prescription department during specified hours, may close the prescription department during its posted hours of operation only if the pharmacist who was scheduled to work cannot do so and a replacement pharmacist cannot reasonably be scheduled to work.

(2) If the prescription department of a pharmacy is closed under the provisions of subsection (a)(1) of this section, the pharmacy shall comply with the requirements of section 20-576-18 of the Regulations of Connecticut State Agencies and the following:

(A) The pharmacy shall implement procedures to notify patients of the pharmacy who need prescriptions dispensed where these prescriptions, including refills, can be obtained immediately. Such procedures may include, but are not limited to, telephone system messages and conspicuously posted signs;

(B) the prescription department of a pharmacy shall not be closed more than one calendar day for any one such closing;

(C) the prescription department of a pharmacy shall not be closed more than eighteen times in a three hundred sixty-five day period or more than twice in any thirty-day period; and

(D) the pharmacist manager shall report each such closing of the prescription department to the commission not later than seventy-two hours after the closing.

(b)(1) A pharmacy that is operated in a store, firm or other business not devoted primarily to the operation of a pharmacy, in accordance with section 20-576-16 of the Regulations of Connecticut State Agencies, may close the pharmacy during its posted hours of operation only if the pharmacist who was scheduled to work cannot do so and a replacement pharmacist cannot reasonably be scheduled to work.

(2) If the pharmacy is closed under the provisions of subsection (b)(1) of this section, the pharmacy shall comply with the requirements of section 20-576-16 of the Regulations of Connecticut State Agencies and the following:

(A) The pharmacy shall implement procedures to notify patients of the pharmacy who need prescriptions dispensed where these prescriptions, including refills, can be obtained immediately. Such procedures may include, but are not limited to, telephone system messages and conspicuously posted signs;

(B) the pharmacy shall not be closed more than one calendar day for any one such closing;

(C) the pharmacy shall not be closed more than eighteen times in a three hundred sixty-five day period or more than twice in any thirty-day period; and

(D) the pharmacist manager shall report each such closing of the pharmacy to the commission not later than seventy-two hours after the closing.

(c) A pharmacy that is not required to post its hours of operation, but closes the pharmacy during its normal hours of operation, shall implement procedures to notify patients of the pharmacy who need prescriptions dispensed where these prescriptions, including refills, can be obtained immediately. Such procedures may include, but are not limited to, telephone system messages and conspicuously posted signs.

Sec. 20-576-19. Disclosure of times of operation of prescription department

Pharmacies which have received approval from the commission to operate when the prescription department is closed shall comply with the following requirements:

(1) The hours of operation of the prescription department shall be posted at all entrances to the pharmacy in block letters at least one-half inch in height;

(2) All advertising for a specific pharmacy shall clearly state the hours of operation of the prescription department; and

(3) All advertising containing multiple listings of specific pharmacies may contain the statement "The services of a pharmacist may not be available at all times when stores are open" in lieu of stating the hours of operation of each pharmacy's prescription department.

Sec. 20-576-20. New pharmacy or relocation of existing pharmacy

(a) The pharmacist manager and applicant for a new pharmacy premise, or the pharmacist manager and licensee of a pharmacy premise which moves its location to a new premise location, or the pharmacist manager and licensee of a pharmacy which complies with sections 20-576-15 and 20-576-16 of the Regulations of Connecticut State Agencies and which moves the area, or any portion thereof, licensed as a pharmacy, to a different area within the business premises, shall appear in person at a meeting of the commission and present a completed new pharmacy premise application or a completed transfer pharmacy premise application with the proper fee and a detailed sketch drawn to scale or a blueprint of the proposed new pharmacy premise location or re-location with its dimensions. The sketch or blueprint shall show at least the following data:

(1) the square footage of the area which will be licensed as the pharmacy premise;

(2) for pharmacies which comply with sections 20-576-15 and 20-576-16 of the Regulations of Connecticut State Agencies, the total square footage of the entire business entity;

(3) the square footage of the prescription department;

(4) the square footage and location of areas used as storerooms or stockrooms;

(5) the size of the prescription counter;
(6) the location of the prescription department sink and refrigerator;
(7) the location of the controlled drug safe;
(8) the location of the toilet facilities;
(9) the location and size of patient counseling areas, if any; and
(10) any other information, related to the physical plant, required by the commission in regulations adopted pursuant to section 20-576(a)(2) of the General Statutes, concerning the licensing of various classes of pharmacies.

(b) Whenever the applicant or the licensee is a person other than the pharmacist manager, the applicant or licensee may designate an individual to act as the applicant's or licensee's agent for purposes of this section.

(c) Applications to move the area, or any portion thereof, licensed as a pharmacy, to a different area within the business premises, for pharmacies which comply with sections 20-576-15 and 20-576-16 of the Regulations of Connecticut State Agencies, shall require the fee for the relocation of a pharmacy.

Sec. 20-576-21. Name of pharmacist manager to be posted

The name of the pharmacist manager shall be conspicuously posted within the prescription department of a pharmacy, or in immediate proximity to it. The manager's name shall be displayed in a location and in a manner so as to be clearly and readily identifiable to patients and customers. Nothing in this section shall be construed to prevent the display of the name of the pharmacist manager at other locations within the pharmacy in addition to the above location.

Sec. 20-576-22. Report of absence of pharmacist manager

(a) If a pharmacist manager is absent from the pharmacy for any reason for more than sixteen consecutive days, the licensee shall immediately report such absence to the commission. The licensee shall provide the commission with the name of the pharmacist designated to be the acting pharmacist manager within five days following the sixteenth consecutive day of the pharmacist manager's absence.

(b) If the absence of the pharmacist manager exceeds forty-two consecutive days such person shall be deemed to have ceased to be the pharmacist manager of the pharmacy. In such case, the licensee shall, in accordance with section 20-597 of the General Statutes, immediately notify the commission and shall immediately enroll with the commission the name, address and license number of the pharmacist who is assuming management of the pharmacy. This notice of change of pharmacist manager shall be accompanied by the filing fee required by section 20-601 of the General Statutes. The pharmacist who ceases management of the pharmacy shall also immediately notify the commission of this fact.

Sec. 20-576-23. Newly designated pharmacist managers

A pharmacist who is designated to be a pharmacist manager and has not previously managed a Connecticut pharmacy, shall appear before the commission for a personal interview related to the pharmacist's knowledge and responsibilities as a pharmacist manager. Such interview shall take place before the pharmacist is authorized to manage the pharmacy except that, in cases of hardship, the pharmacist shall appear at the first commission meeting held after the date the pharmacist commences work as the pharmacist manager.

Sec. 20-576-24. Provision of prescription blanks to prescribing practitioners prohibited

No pharmacist or pharmacy shall provide any prescribing practitioner with prescription blanks bearing a pharmacist's or pharmacy's name thereon.

Sec. 20-576-25. Labeling of prescriptions

All prescriptions dispensed in pharmacies and all outpatient prescriptions dispensed in institutional pharmacies shall be labeled and such labels shall contain all information required by federal and state statutes and regulations.

Sec. 20-576-26. Prescription procedures

(a) Oral orders from a prescribing practitioner or his agent for new prescriptions or oral authorizations for prescription refills shall be communicated directly to a pharmacist. Nothing in this subsection shall be construed to prevent a pharmacy technician from obtaining prescription renewal authorizations in accordance with sections 20-576-35 and 20-576-39 of the Regulations of Connecticut State Agencies.

(b) All electronically transmitted prescriptions shall be received directly in the prescription department of a pharmacy.

Sec. 20-576-27. Substitution of drugs. Definitions

As used in sections 20-576-27 through 20-576-30, inclusive, of the Regulations of Connecticut State Agencies, "Purchaser" means the patient for whom the drug product is prescribed, or the patient's authorized agent, or, in the case of a minor or incompetent person, the patient's parent or guardian except that for subsection (e) of section 20-619 of the General Statutes the word "Purchaser" means the Payor of a prescription drug; and "Substitution" means the dispensing of a different drug, biological, medicinal substance, device or brand of the same in place of the drug, biological, medicinal substance, device or brand of the same prescribed without the express permission of the prescribing practitioner, except as provided in section 20-619 of the General Statutes, or in hospitals without the express approval of the medical staff pharmacy committee.

Sec. 20-576-28. Notification to patient concerning substitution

The pharmacist, prior to any substitution of a drug product pursuant to section 20-619 of the General Statutes, shall notify the patient or the patient's agent of any such substitution. The patient may indicate that no substitution is to be made and that the drug product appearing on the prescription shall be used to the exclusion of all other drug products.

Sec. 20-576-29. Recording of drug substitution

Whenever a pharmacist substitutes a drug product pursuant to section 20-619 of the General Statutes, the pharmacist shall:

(1) Record on the face of the prescription form of a written prescription the brand name of the drug product substituted or if the drug product substituted has no brand name, the generic name and name of the manufacturer of the drug product substituted; or in the case of an oral or electronically transmitted prescription, he shall record both the brand name of the drug product ordered by the prescribing practitioner and the brand name of the drug product substituted or, if the drug product substituted has no brand name, the generic name and name of the manufacturer of the drug product substituted; and

(2) Record on the face of the prescription form the retail price (at the time of dispensing) of the drug product substituted.

Sec. 20-576-30. Disclosing the price of legend drugs

(a) As used in section 20-611 of the General Statutes, and in this section, "prospective purchaser" means a person for whom a prescription has been issued in compliance with section 20-614 of the General Statutes, or the patient's authorized agent or, in the case of a minor or incompetent person, the patient's parent or guardian, and who is making an inquiry either in person or by telephone to a pharmacist for the price of said prescription.

(b) For the purpose of complying with section 20-611 of the General Statutes, and in order to have sufficient information to disclose a prescription price, a pharmacist may ask a prospective purchaser making an inquiry in person or by telephone, or any other person making such an inquiry on behalf of the prospective purchaser for the following:

(1) The name of the medication (brand or generic);

(2) Dose or strength, if applicable; and

(3) Quantity.

(c) In the event that the prospective purchaser or other person making such an inquiry on his or her behalf cannot provide any of the information listed in subsection (b) of this section, and such information is necessary for the requested price to be determined, then the pharmacist may contact the prescribing practitioner in order to obtain the necessary information prior to disclosing the prescription price.

(d) Where substitution of a generic drug product is authorized pursuant to section 20-619 of the General Statutes, the pharmacist shall disclose the price of the substituted drug product. In so doing, however, the pharmacist shall also disclose the brand name or the generic name of said substituted drug product. The pharmacist shall also disclose the name of the drug manufacturer of the substituted drug product and otherwise comply with the provisions of section 20-619 of the General Statutes.

Sec. 20-576-31. Sale of nonlegend drugs in vending machines

No nonlegend drug shall be sold or offered or exposed for sale or dispensed by any means in any type of vending machines.

Regulations Concerning Pharmacy Technicians

Sec. 20-576-32. Pharmacy technicians. Definitions

(a) The definitions in section 20-571 of the CONNECTICUT General Statutes and this section shall apply to sections 20-576-33 [through] TO 20-576-39 inclusive, of the Regulations of Connecticut State Agencies. The term pharmacy technician does not include:

(1) persons working in an institutional pharmacy who are not engaged in the compounding and dispensing of medications, such as stock clerks and clerical personnel; and

(2) persons working in a pharmacy who are not engaged in the compounding and dispensing of medications, such as stock clerks, cashiers, clerical personnel and data entry personnel performing routine functions such as entering and retrieving basic information not directly related to dispensing as defined in subdivision (9) of section 20-571 of the Connecticut General Statutes, getting prescription files and other manual records from storage, generating computer records such as refill logs and inventories of dispensing for the signature or initials of the pharmacist, handling or delivering completed prescriptions to the patient or the patient's agent, and ringing up or receiving sales. Data entry of demographic and insurance information shall not be considered to be directly related to dispensing.

(b) "Supervising pharmacist" means a pharmacist who supervises pharmacy technicians; who is fully aware of and responsible for all activities pertinent to drug preparation, dispensing and distribution in which pharmacy technicians are engaged; and who conducts in-process and final checks on the performance of such pharmacy technicians.

(c) “Certified Pharmacy Technician” means a person who holds an active certification from the pharmacy technician certification board, or any other equivalent pharmacy technician certification approved by the commission of pharmacy.

(d) "Director of pharmacy" means the pharmacist designated by the facility administrator in a care-giving, correctional or juvenile training institution as being in direct charge of, and having overall responsibility for the operation and management of pharmacy services of that institution.

(e) "Inpatient pharmacy" means that area of an institutional pharmacy which is engaged in the manufacture, production, sale and distribution of drugs, devices and other pharmaceutical related materials used in the diagnosis and treatment of registered inpatients of a care-giving, correctional or juvenile training institution.

(f) "Satellite pharmacy" means an extension of an inpatient pharmacy which provides decentralized pharmaceutical care to persons in specific locations within a care-giving, correctional or juvenile training institution, including but not limited to specific patient care areas, nursing units, operating rooms and critical care units.

(g) "Outpatient pharmacy" means that area of an institutional pharmacy which provides pharmaceutical care to registered outpatients receiving treatment at a caregiving institution

Pharmacy Technicians in Institutional Pharmacies

Sec. 20-576-33. Ratio

The ratio of pharmacy technicians to pharmacists in an institutional pharmacy shall be as follows:

(1) In an outpatient pharmacy, the ratio shall not exceed two pharmacy technicians to one supervising pharmacist, except that the commission may, in its discretion, grant a petition based on demonstrated need from any director of pharmacy for a ratio not to exceed three pharmacy technicians to one supervising pharmacist;

(2) In an inpatient pharmacy, the ratio shall not exceed three pharmacy technicians to one supervising pharmacist, except that the commission may, in its discretion, grant a petition based on demonstrated need from any director of pharmacy for a ratio not to exceed five pharmacy technicians to one supervising pharmacist; and

(3) In a satellite pharmacy, the ratio shall not exceed three pharmacy technicians to one supervising pharmacist, except that the commission may, in its discretion, grant a petition based on demonstrated need from any director of pharmacy for a ratio not to exceed five pharmacy technicians to one supervising pharmacist.

Sec. 20-576-34. Supervision and responsibility

The pharmacist providing direct supervision of pharmacy technicians shall be responsible for their actions. Any violations relating to the dispensing of drugs resulting from the actions of pharmacy technicians, or the use of pharmacy technicians in the performance of tasks in a manner not in conformance with section 20-613 of the General Statutes or section 20-576-35 of the Regulations of Connecticut State Agencies, shall constitute cause for action against the license of the supervising pharmacist in accordance with section 20-579 of the General Statutes.

Sec. 20-576-35. Limitations

(a) Pharmacy technicians shall not:

(1) receive new prescription orders verbally from a prescribing practitioner or the practitioner's agent;

(2) consult with a patient or the patient's agent regarding medication, either before or after it has been dispensed, or regarding any medical information contained in a patient medication record system;

(3) perform any identification, evaluation, interpretation or needed clarification of a prescription;

(4) consult with the prescribing practitioner or the practitioner's agent regarding a patient or any medical information pertaining to the patient's prescription;

(5) interpret the clinical data in a patient medication record system;

(6) perform professional consultation with prescribing practitioners, nurses or other health care professionals or their authorized agents;

(7) verify a prescription prior to its release for patient use; and

(8) determine generically and therapeutically equivalent drug products to be substituted for brand name drug products in accordance with section 20-619 of the General Statutes.

(b) Nothing in this section shall be construed to limit a pharmacy technician from communicating with a prescribing practitioner or his agent to obtain an authorization for the renewal of an existing prescription for a drug other than a controlled substance that can no longer be refilled, provided the following conditions are met:

(1) the supervising pharmacist is aware that such an authorization is being requested;

(2) the refill for which the authorization is being requested is identical to the original prescription and there is no change in the prescribed drug, its strength, form, quantity, dose, route of administration or in any other element of the prescription; and

(3) all refill authorizations obtained by the pharmacy technician are reviewed by the supervising pharmacist to insure that there is no change in the prescription.

(c) Pharmacy technicians shall wear name tags or similar forms of identification that clearly identify them to the public as pharmacy technicians.

Pharmacy Technicians in Licensed Pharmacies

Sec. 20-576- 36. Ratio

(a) The ratio of pharmacy technicians to pharmacists shall not exceed two pharmacy technicians to one supervising pharmacist, except that the ratio shall not exceed three pharmacy technicians to one supervising pharmacist:

(1) for intravenous admixtures and other sterile products preparation, unit dose and unit of use dispensing and bulk compounding; [, the ratio shall not exceed three pharmacy technicians to one supervising pharmacist. The commission may, in its discretion, grant a petition based on demonstrated need from any pharmacist manager for a ratio not to exceed three pharmacy technicians to one supervising pharmacist.] ; OR

(2)(A) If at least one of the three pharmacy technicians is a certified pharmacy technician; and

(B) The supervising pharmacist has not, pursuant to the provisions of substection (b) of this section, provided notice to the pharmacist manager that the pharmacist refuses to supervise three pharmacy technicians.

(b) Except for intraveneous admixtures and other sterile products preparation, unit dose and unit of use dispensing and bulk compounding, a pharmacist may refuse to supervise three pharmacy technicians at one time. The pharmacist shall put any such refusal in writing and give it to the pharmacist manager. Any refusal shall include include a specific statement that the

pharmacist refuses to supervise three pharmacy technicians, the names and addresses of the pharmacies involved, the date and the signature of the pharmacist. A pharmacist may rescind any refusal by providing the pharmacist manager with a signed, dated statement. A pharmacy shall keep all refusals or rescissions on file in the pharmacy or a place where they can be easily retrieved and provided to the department.

Sec. 20-576-37. Training

(a) Pharmacy technicians shall complete initial training as determined by the pharmacist manager of each pharmacy. Such training shall include, but not be limited to, on-the-job and other related education and shall be commensurate with the tasks pharmacy technicians are to perform. This training shall be completed prior to the regular performance of such tasks. The pharmacy technician shall be registered with the department no more than thirty days after the start of such training.

(b) The pharmacist manager shall assure the continued competency of pharmacy technicians through continuing in-service training designed to supplement initial training.

(c) The pharmacist manager shall be responsible for maintaining a written record documenting the initial and continuing training of pharmacy technicians and it shall contain the following information:

(1) the name of the individual receiving the training;

(2) the date(s) of the training;

(3) a general description of the topics covered;

(4) the name of the person supervising the training; and

(5) the signature of the individual receiving the training and the pharmacist manager.

When a change of pharmacist manager occurs, the new manager shall review the document and sign it, indicating that he understands its contents. This record shall be readily available for inspection and may be copied by the Commissioner of Consumer Protection or his authorized agents.

Sec. 20-576-38. Supervision and responsibility

The pharmacist providing direct supervision of pharmacy technicians shall be responsible for their actions. Any violations relating to the dispensing of drugs resulting from the actions of pharmacy technicians, or the use of pharmacy technicians in the performance of tasks in a manner not in conformance with section 20-613 of the General Statutes or section 20-576-39 of the Regulations of Connecticut State Agencies, shall constitute cause for action against the license of the supervising pharmacist in accordance with section 20-579 of the General Statutes.

Sec. 20-576-39. Limitations

(a) Pharmacy technicians shall not:

(1) receive new prescription orders verbally from a prescribing practitioner or the practitioner's agent;

(2) consult with a patient or the patient's agent regarding medication, either before or after it has been dispensed, or regarding any medical information contained in a patient medication record system;

(3) perform any identification, evaluation, interpretation or needed clarification of a prescription;

(4) consult with the prescribing practitioner or the practitioner's agent regarding a patient or any medical information pertaining to the patient's prescription;

(5) interpret the clinical data in a patient medication record system;

(6) perform professional consultation with prescribing practitioners, nurses or other health care professionals or their authorized agents;

(7) verify a prescription prior to its release for patient use; or

(8) determine generically and therapeutically equivalent drug products to be substituted for brand name products in accordance with Section 20-619 of the Connecticut General Statutes.

(b) Nothing in this section shall be construed to limit a pharmacy technician from communicating with a prescribing practitioner or his agent to obtain an authorization for the renewal of an existing prescription for a drug other than a controlled substance that can no longer be refilled, provided the following conditions are met:

(1) the supervising pharmacist is aware that such an authorization is being requested;

(2) the refill for which the authorization is being requested is identical to the original prescription and there is no change in the prescribed drug, its strength, form, quantity, dose, route of administration or in any other element of the prescription; and

(3) all refill authorizations obtained by the pharmacy technician are reviewed by the supervising pharmacist to insure that there is no change in the prescription.

(c) Pharmacy technicians shall wear name tags or similar forms of identification that clearly identify them to the public as either pharmacy technicians or certified pharmacy technicians.

Regulations Concerning the Facsimile Transmission of Prescriptions for Legend Drugs

Sec. 20-576-40. Prescriptions transmitted by facsimile machine

No pharmacist or pharmacy shall dispense legend drugs which are not controlled substances upon a prescription transmitted by means of a facsimile machine unless such prescription fully complies with sections 20-576-41 through 20-576-43, inclusive, of the Regulations of Connecticut State Agencies. For the purposes of Sections 20-576-40 through 20-576-43, inclusive, of the Regulations of Connecticut State Agencies, "facsimile machine" means a machine that electronically transmits facsimiles through connection with a telephone network.

Sec. 20-576-41. Requirements

Prescriptions for legend drugs which are not controlled substances may be transmitted by a prescribing practitioner or his agent to a pharmacy by means of a facsimile machine. All such prescriptions must comply with the following in addition to any other requirement of federal or state statute or regulation:

(a) The facsimile prescription shall clearly contain the name of the pharmacy to which the facsimile is being transmitted and the name of the facility from which it is being transmitted if the prescription is written for an inpatient of a chronic or convalescent nursing home or a rest home with nursing supervision;

(b) The facsimile prescription shall clearly display a statement in substantially the following form: "This prescription is valid only if transmitted by means of a facsimile machine"; and

(c) The facsimile document received may be maintained as the actual prescription only if the nature of the equipment and paper ensures that the document will remain non-fading and durable for the minimum amount of time required for the maintenance of prescription records under federal and state statute or regulation. If the document will not remain non-fading or durable, the document transmitted by facsimile machine shall be reduced to writing, photocopied or converted into an individual hard copy printout.

Sec. 20-576-42. Accuracy of prescriptions

If a pharmacist questions the accuracy or authenticity of a prescription order transmitted by facsimile machine, the pharmacist shall contact the prescribing practitioner for verification before dispensing the prescription.

Sec. 20-576-43. Relationship with prescribing practitioners and health care facilities

(a) No pharmacist or pharmacy shall maintain direct telephone, facsimile machine or computer lines to any health care facility or prescribing practitioner's office.

(b) No pharmacist shall enter into any agreement with a prescribing practitioner or health care facility concerning the provision of facsimile machine services or equipment which adversely affects any person's freedom to choose the pharmacy at which a prescription will be filled.

Regulations concerning the Facsimile Transmission of Prescriptions for Controlled Drugs

Sec. 21a-243-12 Definitions

For purposes of sections 21a-243-12 through 21a-243-17 of the regulations of connecticut state agencies, the following terms shall have the meanings indicated:

(a) "Controlled substance" has the meaning given to this term by Connecticut General Statutes, Section 21a-240(9);

(b) "Facsimile machine" means a machine that electronically transmits facsimiles through connection with a telephone network;

(c) "Prescribing practitioner" means any person licensed by the state of Connecticut, any other state, the District of Columbia or the Commonwealth of Puerto Rico and authorized to prescribe controlled substances within the scope of his or her practice; and

(d) “Long term care facility” means a facility or institution as defined by the federal government in 21 CFR 1300.01.

Sec. 21a-243-13. Dispensing of prescriptions transmitted by means of a facsimile machine

No pharmacist or pharmacy may dispense controlled substances upon a prescription transmitted by means of a facsimile machine unless such prescription fully complies with sections 21a-243-14 through 21a-243-18, inclusive, of the regulations of connecticut state agencies.

Sec. 21a-243-14. Schedule II controlled substances

(a) Prescriptions for Schedule II controlled substances may be transmitted by a prescribing practitioner or his agent to a pharmacy by means of a facsimile machine provided the original written, signed prescription is provided to the pharmacist for review prior to the actual dispensing of the controlled substance, except as provided for in subsections (b) and (c) of this section. The original written prescription, once received by the pharmacist, shall be reviewed to ensure that it conforms with the requirements of section 21a-249 of the Connecticut General Statutes and shall be maintained as the original record of dispensing. The facsimile prescription order shall not be considered to be the actual prescription, but only a record of the transmission of the prescription order.

(b) Prescriptions for Schedule II narcotic substances to be compounded for direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may be transmitted by the prescribing practitioner or his agent to a pharmacy by facsimile. The prescription transmitted via facsimile will be accepted as the original prescription for purposes of this section.

(c) Prescriptions for Schedule II controlled substances for patients of a long term care facility may be transmitted by a prescribing practitioner or his agent to the dispensing pharmacy by facsimile. The prescription transmitted via facsimile will be accepted as the original prescription for purposes of this section.

(d) Prescriptions transmitted by facsimile machine in accordance with subsections (b) and (c) of this section shall comply with the requirements set forth in subsection (b) of Section 21a-243-15 of the regulations of connecticut state agencies.

Sec. 21a-243-15. Schedule III, IV and V controlled substances

(a) Prescriptions for Schedule III, IV and V controlled substances may be transmitted by a prescribing practitioner or his agent to a pharmacy by means of a facsimile machine**.**

(b) All prescriptions transmitted pursuant to subsection (a) of this section must comply with the following in addition to any other requirements of federal or state statute or regulation:

(1) The facsimile prescription shall clearly contain the name of the pharmacy to which the facsimile is being transmitted and the name of the facility from which it is transmitted if the prescription is written for an inpatient of a chronic or convalescent nursing home or a rest home with nursing supervision;

(2) The facsimile prescription shall clearly display a statement in substantially the following form: "this prescription is valid only if transmitted by means of a facsimile machine";and

(3) The facsimile document may be maintained as the actual prescription only if the nature of the equipment and paper ensures that the prescription will remain non-fading and durable for the minimum amount of time required for the maintenance of prescription records under federal and state statute and regulation. If the document will not remain non-fading or durable, the prescription transmitted by facsimile machine shall be reduced to writing, photocopied or converted to an individual printout.

Sec. 21a-243-16. Accuracy of prescription

If a pharmacist questions the accuracy or authenticity of a prescription transmitted by facsimile machine, he or she shall contact the prescribing practitioner for verification before dispensing the prescription.

Sec. 21a-243-17. Relationship with prescribing practitioners and health care facilities

(a) No pharmacist or pharmacy shall maintain direct telephone, facsimile machine or computer lines to any health care facility or prescribing practitioner's office.

(b) No pharmacist shall enter into any agreement with a prescribing practitioner or health care facility concerning the provision of facsimile machine services or equipment which adversely affects any person's freedom to choose the pharmacy at which a prescription will be filled.

Sec.21a-243-18. Control of original prescription orders

It shall be the responsibility of the prescribing practitioner to ensure that the prescription form that is used to transmit a prescription by facsimile is either destroyed immediately or marked or controlled in such a manner that prevents the use of such form to obtain controlled substances other than as authorized by these regulations.

Regulations Concerning the Maintenance of Prescription Records using Electronic Data Processing Systems

Computer Records for Legend Drugs

Sec. 20-576-44. Computer system requirements for non-controlled legend drugs

(a) Original written prescriptions for non-controlled substances shall be received, executed and filed in accordance with sections 20-614 and 20-615 of the General Statutes. In the case of original oral prescriptions which shall be received by a pharmacist, an individual or continuous hard copy printout containing all the required information may be used to satisfy the requirement of sections 20-614 and 20-615 of the General Statutes provided that such hard copy prescriptions are maintained in numerical order.

(b) In the case of refills of prescriptions for non-controlled substances an automated data processing system may be used for the storage and retrieval of refill information. Any such computerized system must provide on-line retrieval for a period of at least six months from the date of the last recorded dispensing via visual display device or hard-copy printout of original prescription order information for all prescriptions including those prescription orders which are currently authorized for refilling. This shall include but is not limited to data such as:

(1) the original prescription number;

(2) date of issuance of the original prescription order by the prescribing practitioner;

(3) full name and complete address of the patient;

(4) name and address of the prescribing practitioner;

(5) the name, strength, dosage form, quantity of the substance prescribed and quantity dispensed if different from the quantity prescribed; and

(6) the total number of refills authorized by the prescribing practitioner.

Sec. 20-576-45. Refill history capability requirements

Any computerized system must also provide on line retrieval via visual display device or hard copy printout of the current refill history for all prescription orders which are currently authorized for refilling. This refill history shall include but is not limited to:

(1) the full name and address of the patient;

(2) the full name and complete address of the prescribing practitioner;

(3) the name, strength and dosage form of the substance dispensed;

(4) the date of refill;

(5) the quantity dispensed;

(6) the date on which the prescription was first dispensed;

(7) the original number assigned to said prescription;

(8) the name or initials of the dispensing pharmacists for each refill; and

(9) the total number of refills dispensed to date for that prescription order.

Sec. 20-576-46. Documentation of data requirements

Documentation of the fact that the refill information entered into the computer each time a pharmacist refills an original prescription order for non-controlled substance is correct must be provided by the individual pharmacist who makes use of such a system. In order to accomplish this documentation a pharmacy using such a computerized system must:

(1) provide a separate hardcopy printout of non-controlled substance prescription order refill data for each day. This hard copy printout shall include the refill data mentioned in section 20-576-45 of the Regulations of Connecticut State Agencies except that it need not contain the address of the patient or the address of the prescribing practitioner. The individual pharmacist must verify that the data is correct and sign the document in the same manner as he would sign a check or legal document. This document shall be maintained in a separate file at that pharmacy for a period of three years from the dispensing date. This printout of the non-controlled substance prescription

order refill data for each day must be provided to each pharmacy using such a computerized system within 72 hours of the date on which the refill was dispensed. It must be verified and signed by each pharmacist who effected such dispensing as soon as possible after receipt. In no case shall the printout be verified and signed later than the pharmacist's first work period following receipt of the document; or

(2) In lieu of producing a separate hardcopy printout of non-controlled drug prescription refill data for each day, such data may be maintained in electronic form. If daily refill data is maintained electronically, the electronic data processing system must provide for ready retrieval of this information for a period of three years from the date of the last recorded dispensing. The system must provide on-line retrieval of prescription refill data, via visual display device, for at least six months from the date of the last recorded dispensing. The remaining refill data that must be stored for the required time period may be archived. The name or initials of the pharmacist associated with a prescription refill in the electronic system shall be construed to indicate that such pharmacist was the person responsible for dispensing that prescription. It shall be the responsibility of each dispensing pharmacist to insure that the daily refill information attributed to them is accurate.

Sec. 20-576-47. Information available upon request

Any computerized system shall have the capability of producing a printout of any refill data, for a three year period following the last date of dispensing, which the utilizing pharmacy is responsible for maintaining under Chapter 400j of the General Statutes and the regulations promulgated thereunder. The printout shall be produced within 48 hours of the request, and shall include the following:

(1) the name of the prescribing practitioner;

(2) the name of the patient;

(3) the name, dosage form, strength and quantity of the drug;

(4) the date of dispensing for each refill;

(5) the name or initials of the dispensing pharmacist; and

(6) the number of the original prescription order.

Any pharmacy utilizing a computerized system, and authorized to maintain records at a central record keeping location, must be capable of obtaining the requested printout within 48 hours.

Sec. 20-576-48. Auxiliary system provision

In the event that a pharmacy which employs such a computerized system experiences system downtime, the pharmacy shall have an auxiliary procedure to be used for documentation of refills of non-controlled substance prescription orders. This auxiliary procedure shall insure that refills are authorized by the original prescription order, and that all of the appropriate data are retained for on-line entry as soon as the computer system is available for use again. All prescriptions refilled during the down time shall be confirmed as being authorized upon the resumption of on-line service.

Sec. 20-576-49. When handwritten system allowed

If an automated data processing system is used for the storage and retrieval of refill information for prescription orders as authorized by section 20-576 of the General Statutes and the regulations promulgated thereunder, the pharmacy may use a traditional handwritten system only to satisfy the requirements of section 20-576-48 of the Regulations of Connecticut State Agencies.

Sec. 20-576-50. Notice to commission upon commencement of use or change

Any pharmacy instituting an automated data processing system, or changing to an entirely new system, for the storage and retrieval of refill information for prescription orders as authorized by section 20-576 of the General Statutes and the regulations promulgated thereunder shall notify the commission at least 30 days prior to the commencement of usage of said system.

Sec. 20-576-51. Requirement of safeguards

If an automated data processing system is used for the storage and retrieval of refill information for prescription orders as authorized by section 20-576 of the General Statutes and the regulations promulgated thereunder, it shall:

(1) guarantee the confidentiality of the information contained in the data bank; and

(2) be capable of providing safeguards against erasures and/or unauthorized changes in data after the information has been entered and verified by the pharmacist.

Sec. 20-576-52. Reconstruction of data in case of accident

If an automated data processing system is used for the storage and retrieval of re-fill information for prescription orders as authorized by section 20-576 of the General Statutes and the regulations promulgated thereunder, said automated data processing system shall be capable of being reconstructed in the event of a computer malfunction or accident resulting in the destruction of the data bank.

Sec. 20-576-53. Discontinuance of data processing system

In the event that a pharmacy using an electronic data processing system for storage and retrieval of information goes out of business, sells out to another pharmacy that does not wish to use such a system, or discontinues use of the computer system, the pharmacy shall:

(1) Notify the commission in writing at least 30 days prior to discontinuance of said system;

(2) Provide an up-to-date hardcopy printout of all prescriptions stored in the automated system for three years as part of the final records of that pharmacy prior to a change over to a manual system; and

(3) Make provision for these records to be available to any nearby pharmacy in the event that the pharmacy closes, as provided in Section 20-615 of the general statutes.

Regulations Concerning Computer Records for Controlled Drugs

Sec. 21a-244-1. Computer system requirements

(a) All prescriptions for schedule II controlled substances, and original written and oral prescriptions for schedule III, IV and V controlled substances shall be received, executed and filed in accordance with sections 21a-249 and 21a-250 of the Connecticut General Statutes and all applicable federal laws and regulations. In the case of original oral prescriptions for schedule III, IV and V controlled substances, which shall be received by a pharmacist, an individual hard copy printout of the prescription containing all required information may be used to satisfy the requirements of section 21a-249(d) of the Connecticut General Statutes.

(b) In the case of refills of prescriptions for schedule III, IV and V controlled substances, an automated data processing system may be used for the storage and retrieval of refill information. Any such computerized system shall provide on-line retrieval for a period of at least six months from the date of the last recorded dispensing via visual display device or hardcopy printout of original prescription order information for all prescriptions including those prescription orders which are currently authorized for refilling. This shall include but is not limited to data such as:

(1) the original prescription number;

(2) the date of issuance of the original prescription order by the prescribing practitioner;

(3) the full name and complete address of the patient;

(4) the full name, full address, and Drug Enforcement Administration, United States Department of Justice, or its successor agency registration number of the prescribing practitioner;

(5) the name, strength, dosage form, quantity of the controlled substance prescribed and quantity dispensed if different from the quantity prescribed; and

(6) the total number of refills authorized by the prescribing practitioner.

Sec. 21a-244-2. Refill history capability requirement

Any computerized system must also provide on line retrieval via visual display device or hard copy printout of the current refill history for Schedule III, IV, or V controlled substance prescription orders which are currently authorized for refilling. This refill history shall include but is not limited to:

(a) the full name and address of patient;

(b) the full name and complete address of the prescribing practitioner;

(c) the name, strength and dosage form of the controlled substance;

(d) the date of refill;

(e) the quantity dispensed;

(f) the date on which the prescription was first dispensed;

(g) the original number assigned to said prescription;

(h) the name or initials of the dispensing pharmacist for each refill; and

(i) the total number of refills dispensed to date for that prescription order.

Sec. 21a-244-3. Documentation of data requirement

Documentation of the fact that the refill information entered into the computer each time a pharmacist refills an original prescription order for a Schedule III, IV or V controlled substance is correct must be provided by the individual pharmacist who makes use of such a system. In order to accomplish this documentation, a pharmacy using such a computerized system must provide either;

(1) a separate hard-copy printout of controlled substance prescription order refill data for each day. This hard copy printout shall include the refill data mentioned in section 21a-244-2 of the regulations of connecticut state agencies except that it need not contain the address of the patient or the address of the prescribing practitioner. Each prescription on said printout shall be reviewed by each individual pharmacist who refilled such a prescription order. The individual pharmacist must verify that the data indicated is correct and then sign this document in the same manner as he would sign a check or legal document. This document shall be maintained in a separate file at that pharmacy for a period of three years from the dispensing date. This printout of the controlled substance prescription order refill data must be provided by each pharmacy using such a computerized system within 72 hours of the date on which the refill was dispensed and must be verified and signed by each pharmacist who effected such dispensing as soon as possible after receipt. In no case shall the printout be verified and signed later than the pharmacist's first work period following receipt of the document[.]; OR

(2) In lieu of producing a hardcopy printout of daily refill information signed by each dispensing pharmacist, the pharmacy shall maintain a bound log book or separate file which each pharmacist involved in such dispensing shall sign in the same manner as he would sign a check or legal document. The signature of the dispensing pharmacist shall indicate that he has reviewed the refill information entered into the computer, which is attributed to him, for each date of dispensing and that it is correct as shown. Whenever possible this log book or separate file shall be signed by each pharmacist on the date of dispensing but in no case shall it be signed later than the pharmacist's first work period in that pharmacy after such date.

Sec. 21a-244-4. Information available to commissioner upon request

Any computerized system shall have the capability of producing a printout of any refill data which the utilizing pharmacy is responsible for maintaining under Chapter 420b of the general statutes and the regulations promulgated thereunder. This shall include the capability to produce a refill by refill audit trail for any specified strength and dosage form of any controlled substance by either brand or generic name or both. Said printout shall be produced within 48 hours and shall indicate the following:

(a) the name of the prescribing practitioner;
(b) the name and address of the patient;
(c) the name, dosage form, strength, and quantity of the drug dispensed on each refill;
(d) the name or initials of the dispensing pharmacist and the date of dispensing for each refill; and
(f) the number of the original prescription order.

Any pharmacy utilizing a computerized system and authorized to maintain records a a central record-keeping location, must be capable of obtaining the requested printout within 48 hours.

Sec. 21a-244-5. Auxiliary system provision

In the event that a pharmacy which employs such a computerized system experiences system down-time, the pharmacy must have an auxiliary procedure which will be used for documentation of re-fills of Schedule III, IV or V controlled substance prescription orders. This auxiliary procedure must insure that refills are authorized by the original prescription order and that all of the appropriate data is retained for on-line data entry as soon as the computer system is available for use again. All prescriptions refilled during the down-time shall be confirmed as being authorized upon resumption of on-line service.

Sec. 21a-244-6. When handwritten system is allowed

If an automated data processing system is used for the storage and retrieval or refill information for prescription orders as authorized by Section 21a-244 of the general statutes, and the regulations promulgated thereunder, the pharmacy may use a traditional, handwritten system only to satisfy the requirement of Section 21a-244-5 of the regulations of State agencies.

Sec. 21a-244-7. Notice to commissioner upon commencement of use Any pharmacy instituting an automated data processing system for the storage and retrieval of refill information for prescription orders as authorized by Section 21a-244 of the general statutes and the regulations promulgated thereunder shall notify in writing the Drug Control Division of the Department of Consumer Protection at least 30 days prior to the commencement of usage of said system.

Sec. 21a-244-8. Compliance with federal law

Notwithstanding the provisions of Section 21a-244 of the general statutes and the regulations promulgated thereunder, there must be compliance with all applicable federal laws.

Sec. 21a-244-9. Requirement of safeguards

If an automated data processing system is used for the storage and retrieval of refill information for prescription orders as authorized by Section 21a-244 of the general statutes and the regulations promulgated thereunder, it shall:

(a) guarantee the confidentiality of the information contained in the data bank; and

(b) be capable of providing safeguards against erasures and unauthorized changes in data after the information has been entered and verified by the pharmacist.

Sec. 21a-244-10. Reconstruction of data in case of accident

If an automated data processing system is used for the storage and retrieval of refill information for prescription orders as authorized by Section 21a-244 of the general statutes and the regulations promulgated thereunder, said automated data processing system shall be capable of being reconstructed in the event of a computer malfunction or accident resulting in the destruction of the data bank.

Sec. 21a-244-11. Discontinuance of data processing system

In the event that a pharmacy using an electronic data processing system for storage and retrieval of information goes out of business, sells out to another pharmacy that does not wish to use such a system, or discontinues use of the computer system, the pharmacy shall:

(a) notify the Drug Control Division of the Department of Consumer Protection in writing at least 30 days prior to discontinuance of said system;

(b) provide an up-date hard-copy printout of all prescriptions stored in the automated system for the three years immediately preceding as part of the final records of that pharmacy prior to a change over to a manual system; and

(c) make provision for these records to be available to any nearby pharmacy in the event that the pharmacy closes, as provided in Section 20-615 of the general statutes.

Regulations Establishing the Use of Electronic Data Processing Systems for Maintaining Drug Records in Hospitals.

Section 21a-244a-1. Definitions

As used in section 21a-244a-2 to section 21a-244a-4, inclusive, of the Regulations of Connecticut State Agencies:

(1) "Drug record" means "drug record" as defined in section 21a-244a of the Connecticut General Statutes; and

(2) "Hospital" means "hospital" as defined in section 19a-490 of the Connecticut General Statutes.

Section 21a-244a-2. Use of Electronic Data Processing System

Hospitals may create and maintain drug records using an electronic data processing system, provided they comply with the requirements of sections 21a-244a-3 and 21a-244a-4 of the Regulations of Connecticut State Agencies.

Section 21a-244a-3. Establishment of Policy

Hospitals shall establish and comply with a policy in creating and maintaining electronic drug records. This policy shall be maintained electronically or in writing, shall be dated and shall accurately reflect the manner in which electronic drug records are currently created and maintained at the hospital. This policy shall be readily available for inspection by the Department of Consumer Protection for a period of three years from its last effective date.

Section 21a-244a-4. Content of Policy

A hospital, in establishing the policy required by section 21a-244a-3 of the Regulations of Connecticut State Agencies, shall include:

(1) a description of the electronic data processing system being used by the hospital to create and maintain records. This description shall include at least the following information:

(A) the specific types of drug records being maintained electronically on the system; and

(B) the hospital's patient populations and physical locations for which the electronic drug record system is being utilized;

(2) the specific types of electronic identifiers, including but not limited to those listed in section 21a-244a(c) of the Connecticut General Statutes, that are utilized to access the hospital's electronic system, or used in place of written signatures or initials where required. All electronic identifiers described in the system shall be unique to an individual and shall be controlled in a secure manner;

(3) the manner in which access to the electronic drug record system is controlled. This shall, at a minimum, include:

(A) a description of the general levels of access into the system; and

(B) the mechanism by which the hospital identifies all individuals having access to the electronic system, their level of access and a description of how this access data is maintained by the hospital;

(4) the method by which individual electronic identifiers allowing access to the system are issued, maintained and terminated. This shall include, at a minimum, the following information:

(A) the specific individual or group at the hospital responsible for issuing, maintaining or terminating electronic identifiers;

(B) the procedure by which electronic identifiers are issued, maintained and terminated; and

(C) the method by which the uniqueness of electronic identifiers is established and their security maintained;

(5) the system by which electronic drug records are stored on-line, archived or maintained in some other manner that ensures that they are readily retrievable for a period of not less than three years;

(6) the recovery procedure utilized to reconstruct electronic drug records in the event the system experiences unscheduled downtime;

(7) the procedure utilized to routinely backup data stored on the electronic system to prevent the loss or destruction of electronic drug records;

(8) the method employed to prevent or detect unauthorized alteration or erasure of electronic drug records maintained on the system; and

(9) the procedure employed to ensure that all information contained in electronic drug records that is deemed to be confidential is appropriately protected from unauthorized access and dissemination. Such confidential information shall, at a minimum, include the names of patients and prescribing practitioners. The electronic data processing system shall comply with all federal and state records. **(Effective 8/99)**

Regulations Concerning Classes of Pharmacies

Sec. 20-576-54. Definitions

As used in sections 20-576-54 to 20-576-59, inclusive, of the Regulations of Connecticut State Agencies:

(1) "Commission" means the Commission of Pharmacy;

(2) "Community pharmacy" means a pharmacy licensed under section 20-594 of the Connecticut General Statutes wherein legend drugs and legend devices are stored and dispensed and from which related pharmaceutical care services are provided, primarily to non-institutionalized patients living in a community setting;

(3) "Infusion therapy pharmacy" means a pharmacy licensed under section 20-594 of the Connecticut General Statutes wherein legend drugs, in the form of parenteral, enteral and infusion therapies, and legend devices are stored, dispensed or sold and from which related pharmaceutical care services are provided;

(4) "Long-term care pharmacy" means a pharmacy licensed under section 20-594 of the Connecticut General Statutes wherein legend drugs and legend devices are stored and dispensed to patients or residents of licensed nursing homes, rest homes, homes for the aged, or other supervised residential facilities and from which related pharmaceutical care services are provided. This includes pharmacies located both inside and outside of such facilities but does not include those that are part of a licensed hospital;

(5) "Nuclear pharmacy" means a pharmacy licensed under section 20-594 of the Connecticut General Statutes wherein legend drugs, in the form of radiopharmaceuticals, and legend devices are stored, prepared or dispensed and from which related radiopharmaceutical care services are provided;

(6) "Specialized drug pharmacy" means a pharmacy licensed under section 20-594 of the Connecticut General Statutes wherein specialized legend drugs and legend devices are stored and dispensed and from which related pharmaceutical care services are provided including, but not limited to, those relating to the treatment of diabetes, hemophilia and infertility;

(7) "Specialty pharmacy" means a pharmacy licensed under section 20-594 of the Connecticut General Statutes that does not meet any of the other definitions listed in subdivisions (2) through (6), inclusive, of this section.

Sec. 20-576-55. Classes of pharmacies

The commission shall approve a pharmacy for licensure in one or more of the following classes:

(1) Community pharmacy;
(2) Infusion therapy pharmacy;
(3) Long-term care pharmacy;
(4) Nuclear pharmacy; or
(5) Specialized drug pharmacy; or
(6) Specialty pharmacy.

Sec. 20-576-56. Practice of pharmacy in classes

The commission shall approve each pharmacy to practice in one or more classes, as listed in section 20-576-55 of the Regulations of Connecticut State Agencies. No pharmacy shall conduct any substantial portion of its business in a class or classes until it is approved to do so by the commission, except that no pharmacy licensed prior to the effective date of this section shall be in violation of this section if the commission has not yet approved the pharmacy to practice in one or more classes.

Sec. 20-576-57. Designation of class

(a) The commission shall, when approving a new pharmacy license application, designate the class or classes, as listed in section 20-576-55 of the Regulations of Connecticut State Agencies, in which the pharmacy is approved for licensure. The commission has complete discretion to determine in which class or classes a pharmacy shall be licensed. In making its determination, the commission shall take into consideration the proportion of the business that the class of service represents as it relates to the total business of the pharmacy.

(b) For pharmacies licensed prior to the adoption of sections 20-576-54 to 20-576-59, inclusive, of the Regulations of Connecticut State Agencies, the commission shall review the operation of each such pharmacy and designate the class or classes in which it is approved for

licensure not later than one hundred eighty days after the effective date of section 20-576-56 of the Regulations of Connecticut State Agencies.

(c) The licensing of a pharmacy in more than one class, simultaneously, shall not result in an increase in the licensing fee.

Sec. 20-576-58. Request for reconsideration. Modifications.

(a) A pharmacy may request the commission to reconsider the pharmacy's initial designation of class not later than thirty days after the notice of such classification.

(b) A pharmacy that is licensed to operate in a particular class or classes may apply to the commission for a modification of such status.

(c) No fee shall be charged for a request for reconsideration or modification.

Sec. 20-576-59. Waivers and modifications

(a) Upon written request, the commission may grant a waiver or modification of any regulation pertaining to the operation of a pharmacy within a designated class or classes. The commission may approve such a request if it finds that:

(1) The waiver or modification will not adversely affect the health, safety or welfare of the public;

(2) The basis for the request has been clearly substantiated; and

(3) Compliance with the particular regulation is, or will be, impractical or unduly burdensome.

(b) For the purpose of requesting the waiver or modification described in subsection (a) of this section, the pharmacist manager, as designated under the provisions of section 20-597 of the Connecticut General Statutes, shall submit a written request to the commission which documents:

(1) The specific regulation for which the waiver or modification is requested;

(2) The reason for the request;

(3) A description of any alternative measures that will be employed;

(4) Any other relevant information that will assist the commission in properly evaluating the request; and

(5) Any additional information that may be requested by the commission for purposes of evaluating the request.

(c) Upon approving or denying the request, the commission shall notify the pharmacist manager of its decision. Any approval shall state the specific regulation or regulations being waived or modified, and any contingent conditions the pharmacy is required to meet in order to obtain the waiver or modification.

Regulations Concerning Nuclear Pharmacy

Sec. 20-175-75. Purpose and scope

(a) It is unlawful for any person to provide radiopharmaceutical services unless he is a nuclear pharmacist or a person performing radiopharmaceutical services under the supervision of a nuclear pharmacist acting in accordance with state statute and regulations enacted by the commission of pharmacy, the department of environmental protection, and the United States Nuclear Regulatory Commission. An exemption from these regulations is granted to:

(1) United States Nuclear Regulatory Commission authorized practitioners; and

(2) United States Nuclear Regulatory Commission authorized institutions which prepare radiopharmaceuticals for their own use and which employ or contract with such authorized practitioners to prepare radiopharmaceuticals for their own use.

(b) The requirements of Secs. 20-175-75--20-175-80, inclusive, are not in lieu of, other applicable provisions of regulations of the commission of pharmacy, the United States Nuclear Regulatory Commission and other state and federal agencies.
(Effective June 16, 1982)

Sec. 20-175-76. Definitions

(a) As used in Secs. 20-175-75--20-175-80, inclusive:

(1) "Nuclear pharmacy" means a pharmacy providing radiopharmaceutical services;

(2) The term of "Radiopharmaceutical service" includes, but is not limited to, the compounding, dispensing, labeling and delivery of radiopharmaceuticals; the participation in radiopharmaceutical utilization reviews; the proper and safe storage and distribution of radiopharmaceuticals; the maintenance of radiopharmaceutical quality assurance; and the offering of those acts, services, operations or transactions necessary in the conduct, operation, management and control of a nuclear pharmacy;

(3) A "Radiopharmaceutical" means any substance defined as a drug in Section 201(g)(1) of the Federal Food, Drug and Cosmetic Act which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any such drug which is intended to be made radioactive. This definition includes non-radioactive reagent kits and nuclide generators which are intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds or potassium-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides;

(4) The term "Radiopharmaceutical quality assurance" includes, but is not limited to, the performance of appropriate chemical, biological and physical tests on radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals, including internal test assessment, authentication of product history and the keeping of proper records;

(5) The term "Internal test assessment" includes, but is not limited to, conducting those tests necessary to insure the integrity of the test;

(6) The term "Authentication of product history" includes, but is not limited to, identifying the purchasing source, the ultimate use or disposition and any intermediate handling of any components of a radiopharmaceutical; and

(7) "Authorized practitioner" means a practitioner duly authorized by applicable federal and state law to possess, use and administer radiopharmaceuticals.

(b) Where the term "direct supervision" is used it shall be deemed to require that the supervising licensed nuclear pharmacist shall be physically present in the general area or location where the supportive personnel are performing supportive duties and shall conduct inprocess and final checks.

Sec. 20-175-77. General requirements for pharmacies providing radiopharmaceutical service

(a) The application for a permit to operate a pharmacy providing radiopharmaceutical services shall only be issued to a qualified nuclear pharmacist. All personnel performing tasks in the preparation and distribution of radioactive drugs shall be under the direct supervision of the nuclear pharmacist. A nuclear pharmacist is responsible for all operations of the licensed area and shall be in personal attendance at all times that the nuclear pharmacy is open for business.

(b) Nuclear pharmacies shall have adequate space, commensurate with the scope of services required and provided, meeting minimal space requirements established for all pharmacies in the state. The nuclear pharmacy shall be separate from the pharmacy areas for non-radioactive drugs and shall be inaccessible to all unauthorized personnel. All pharmacies handling radiopharmaceuticals shall be provided with a radioactive storage and decay area. A nuclear pharmacy handling radioactive drugs exclusively may be exempted from the general space requirements for pharmacies by obtaining a waiver from the commission of pharmacy. Detailed floor plans shall be submitted to the commission of pharmacy prior to said commission's approval of the license.

(c) The process used for handling radioactive materials by any license holder in Connecticut must involve appropriate procedures for the purchase, receipt, storage, manipulation, compounding, distribution and disposal of radioactive materials. In order to insure the public health and safety in this respect, a nuclear pharmacy in Connecticut shall first meet the following general requirements:

(1) The environment where the handling of radioactive materials takes place shall be properly ventilated so that radioactive materials cannot be airborne from that environment to other non-occupationally unrestricted areas;

(2) The environment shall be properly shielded so that radiation cannot impinge upon persons or objects in surrounding environments;

(3) The environment shall be properly located so that the receipt and dispersal of radioactive materials does not result in inadvertent and undesired contamination of other non-occupationally labeled areas;

(4) The area shall be designed in such a manner that radioactive materials can be contained in given areas to ensure adequate safety and protection to personnel working in them and to insure proper operation of the corresponding assay equipment; and

(5) The environment shall be constructed, operated and designed in such a manner that no one radioactive material can contaminate another material and therefore vitiate or adulterate other potential drugs or drug ingredients, radioactive or not.

(d) Nuclear pharmacies shall maintain records of acquisition and disposition of all radioactive drugs in accordance with rules and regulations of the United States Nuclear Regulatory Commission.

(e) In addition to any labeling requirements of the commission of pharmacy for non-radioactive drugs, the immediate outer container of a radioactive drug to be dispensed shall also be labeled with:

(1) The standard radiation symbol;

(2) The words, "CAUTION-RADIOACTIVE MATERIAL";

(3) The radionuclide;

(4) The chemical form;

(5) The amount of radioactive material contained in millicuries or microcuries;

(6) If a liquid, the volume in cubic centimeters;

(7) The requested calibration time for the radioactivity contained;

(8) The name, address and telephone number of the nuclear pharmacy;

(9) The prescription number; and

(10) The date.

(f) The immediate container shall be labeled with:

(1) The standard radiation symbol;

(2) The words, "CAUTION-RADIOACTIVE MATERIAL";

(3) The name, address and telephone number of the nuclear pharmacy;

(4) The prescription number; and

(5) The name of the radiopharmaceutical.

(g) Prior to dispensing the radiopharmaceutical the nuclear pharmacist shall:

(1) Measure the total activity of each radiopharmaceutical dosage except for:

(a) Those radiopharmaceuticals containing less than 10 microcuries; or

(b) A pure beta-emitting radionuclide;

(2) Verify that smaller dosages contain less than 10 microcuries; and

(3) Keep a record of the measurements.

(h) Nuclear pharmacies may redistribute United States Food and Drug Administration approved radioactive drugs if the nuclear pharmacy does not process the radioactive drugs in any manner nor violate the product packaging.

(i) Nuclear pharmacies shall only dispense radio- pharmaceuticals which comply with acceptable professional standards of radiopharmaceutical quality assurance.

(j) A nuclear pharmacist may transfer to authorized persons and United States Nuclear Regulatory Commission licensed medical practitioners radioactive materials not intended for drug use, in accordance with regulations of the United States Nuclear Regulatory Commission and the regulations of the Connecticut department of environmental protection. A nuclear pharmacy may also furnish radiopharmaceuticals for office use to these practitioners for individual patient use.

(k) Nuclear pharmacies shall comply with all applicable laws and regulations of federal and state agencies including those laws and regulations governing non-radioactive drugs. For nuclear pharmacies handling radiopharmaceuticals exclusively, the commission of pharmacy may waive regulations pertaining to the pharmacy permits of nonradiopharmaceuticals for requirements that do not pertain to the practice of nuclear pharmacy.

(l) Radioactive drugs are to be dispensed only upon a non-refillable prescription order from a United States Nuclear Regulatory Commission licensed medical practitioner authorized to possess, use and administer radiopharmaceuticals.

Sec. 20-175-78. General requirements for a nuclear pharmacist

(a) A qualified nuclear pharmacist shall:

(1) Be a pharmacist licensed to practice in the state of Connecticut;

(2) Meet minimal standards of training and experience in the handling of radioactive materials in accordance with the requirements of the United States Nuclear Regulatory Commission and the Connecticut department of environmental protection; and

(3) Present to the commission of pharmacy the following evidence of education and experience:

(A) Certification that the pharmacist has completed a minimum of six months on the job training under the supervision of a qualified nuclear pharmacist in a nuclear pharmacy providing radiopharmaceutical services; and

(B) Certification that the pharmacist has completed a nuclear pharmacy training program in an accredited college of pharmacy; or

(C) An affidavit of experience and training, in lieu of (A) and (B).

(b) The commission of pharmacy may grant partial or equivalent credit for education and experience gained in non-approved programs, if, in the opinion of the commission, such programs provide the same or equal level of competence as approved programs.

Sec. 20-175-79. Minimum requirements for space, equipment, supplies and library

(a) Each nuclear pharmacy must meet the following requirements for space:

(1) The area for the storage, compounding and dispensing of radioactive drugs shall be completely separate from pharmacy areas for nonradioactive drugs;

(2) Hot lab and storage area shall be a minimum of one hundred twenty (120) square feet; and

(3) The compounding and dispensing area shall be a minimum of three hundred (300) square feet.

(b) Each nuclear pharmacy shall be equipped with at least the following items of equipment:

(1) Dose calibrator;

(2) Refrigerator;

(3) Drawing station;

(4) Well scintillation counter;

(5) Incubator oven;

(6) Microscope;

(7) Chromatagraphic apparatus or comparable means of effectively assuring tagging efficiency;

(8) Portable radiation survey meter capable of detecting 0.005 microcuries of activity of any radionuclides utilized; and

(9) Other equipment deemed necessary for radio- pharmaceutical quality control for products compounded or dispensed as may be determined by the United States Nuclear Regulatory Commission and/or by the commission of pharmacy. Disposal of equipment will be made in accordance with all lawful requirements of the United States Nuclear Regulatory Commission, the department of consumer protection and the department of environmental protection.

(c) Each nuclear pharmacy must have the following supplies on hand at all times:

(1) Disposable syringes (1, 3, and 5 cc);

(2) Multidose vials (10, and 20 cc);

(3) Disposable alcohol swabs;

(4) Disposable gloves;

(5) Appropriate labels for radioactive drugs; and

(6) Other supplies necessary for drugs to be compounded or dispensed as may be determined by the United States Nuclear Regulatory Commission and/or the commission of pharmacy. Disposal of supplies shall be made in accordance with all lawful requirements of the United States Nuclear Regulatory Commission, the department of consumer protection and the department of environmental protection.

(d) Each nuclear pharmacy shall have on the premises the following reference books. All books must be current editions or revisions:

(1) United Pharmacopeia-National Formulary with supplements

(2) State statutes and regulations relating to pharmacy;

(3) State and federal regulations governing the use of applicable radioactive materials; and

(4) United States Public Health Service Radiological Health Handbook.

Sec. 20-175-80. Quality control

The holder of a nuclear pharmacy license is responsible for the radioactive pharmaceutical quality control of all drugs, including biologicals, dispensed or manufactured. Radioactive pharmaceutical quality controls include, but are not limited to, the carrying out and interpretation of data resulting from chemical, biologicals and physical tests on potentially radioactive pharmaceuticals to determine the suitability for use in human and other animals, including internal test assessment and authentication of product history. Effective: June 16, 1982)

Regulations Establishing Quality Assurance Programs to Detect, Identify and Prevent Prescription Errors

Section 20-635-1. Definitions

As used in section 20-635-1 to section 20-635-6, inclusive, of the Regulations of Connecticut State Agencies:

(1) "Department" means the Department of Consumer Protection;

(2) "Pharmacy personnel" means pharmacist, pharmacy intern, pharmacy technician, and pharmacy support personnel; and

(3) "Prescription error" means "prescription error" as defined by section 20-635 of the Connecticut General Statutes.

Section 20-635-2. Quality assurance program

(a) Each pharmacy shall implement a quality assurance program to detect, identify and prevent prescription errors. The quality assurance program shall document and assess prescription errors to determine the cause and an appropriate response.

(b) The primary purpose of the quality assurance program shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a prescription error to assess the cause and any contributing factors such as system or process failures.

(c) Each pharmacy shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent prescription errors.

Section 20-635-3. Notification to patient and prescribing practitioner

(a) Unless informed of a prescription error by the prescribing practitioner or the patient, a pharmacist who has discovered or been informed of a prescription error, shall immediately notify the patient and the prescribing practitioner that a prescription error has occurred. If the patient is deceased or unable to fully comprehend the notification of the error, the pharmacist shall notify the patient's caregiver or appropriate family member.

(b) The pharmacist shall communicate to the patient and prescribing practitioner the methods for correcting the error and reducing the negative impact of the error on the patient.

Section 20-635-4. Review of prescription errors

(a) Each pharmacy shall perform a quality assurance review for each prescription error. This review shall commence as soon as is reasonably possible, but no later than two business days from the date the prescription error is discovered.

(b) Each pharmacy shall create a record of every quality assurance review. This record shall contain at least the following:

(1) the date or dates of the quality assurance review and the names and titles of the persons performing the review;

(2) the pertinent data and other information relating to the prescription error reviewed;

(3) documentation of the patient and prescribing practitioner contact required by section 20-635-3 of the Regulations of Connecticut State Agencies;

(4) the findings and determinations generated by the quality assurance review; and

(5) recommended changes to pharmacy policy, procedure, systems, or processes, if any.

Section 20-635-5. Records

(a) Each pharmacy shall maintain a written copy of the quality assurance program on the pharmacy premises. This copy shall be readily available to all pharmacy personnel and the department.

(b) Each pharmacy shall maintain a record of the quality assurance review for all prescription errors for a minimum of three years. These records shall be maintained in an orderly manner and filed by date. These records, which may be stored outside of the pharmacy, shall be made available for inspection by the department within forty-eight (48) hours of request.

Section 20-635-6. Notice to pharmacy personnel

(a) A pharmacy shall make available a copy of its quality assurance program to each pharmacist employed at the pharmacy.

(b) Each pharmacy shall notify all pharmacy personnel that the discovery or reporting of a prescription error shall be relayed immediately to a pharmacist on duty.

(c) Each pharmacy shall inform pharmacy personnel of changes to pharmacy policy, procedure, systems, or processes made as a result of recommendations generated by the quality assurance program.

Regulations Concerning the Safe Handling and Disposal of Hypodermic Needles and Syringes

Sec. 21a-66-1. Definitions.

(a) Hypodermic needles and syringes means needles, syringes and any other types of intravascular device including but not limited to indwelling catheters and introducers, except that needles which are specifically used to administer antineoplastic agents shall be handled in accordance with existing Department of Environmental Protection Regulations for the handling of such wastes.

(b) Biomedical Waste means untreated solid waste which requires special handling as defined in Sec. 22a-207(17) of the Connecticut General Statutes.

(c) Treatment when used in connection with biomedical waste, means any method, technique, or process which is designed to change the character or composition of any biomedical waste so as to render such waste non-infectious, non-injurious, safer for storage, for transport, and reduced in volume.

Sec. 21a-66-2. Safety procedures concerning hypodermic needles and syringes.

Each health-care institution licensed pursuant to Chapter 368v of the Connecticut General Statutes, each laboratory licensed pursuant to Section 19a-30 of the Connecticut General Statutes, and all other generators of biomedical waste as defined in Section 22a-207 of the Connecticut General Statutes, as amended, shall forthwith establish and implement procedures for the handling and disposal of hypodermic needles and syringes in accordance with the following safety and control measures.

(a) Used hypodermic needles and syringes shall be placed intact directly into rigid puncture-resistant containers and the following procedure shall be followed:

(1) Needles shall not be resheathed, purposely bent, broken, removed from disposable syringes, or otherwise manipulated by hand;

(2) Notwithstanding the requirement set forth in subsection (a)(1), injectable equipment having self-contained secondary precautionary type sheathing devices may be utilized in accordance with its manufacturer's directions, and resheathing may occur when technical procedure involved requires resheathing as part of that procedure;

(3) Containers shall be located in close proximity to the area in which hypodermic needles and syringes are used to minimize the hazards of injury or transmission of infection during transport;

(4) The container lid opening shall be a one way system to prevent spillage, and this shall render the items contained therein nonreuseable;

(5) Containers shall be maintained under secure conditions at all times; and

(6) Prior to treatment, containers shall be stored in a designated area accessible only to authorized personnel.

(b) Containers of hypodermic needles and syringes shall be considered to be biomedical waste, and shall be treated to render them non-recoverable in accordance with any existing Department of Environmental Protection Regulations regarding biomedical waste or in accordance with any other methods specifically approved by the Commissioner of Consumer Protection in consultation with the Commissioners of Health Services and Environmental Protection.

(c) If treatment is not done onsite, these wastes shall be safely transported in sealed, impervious containers to another facility for appropriate treatment.

(d) Personnel involved in the handling and disposal of hypodermic needles and syringes shall be informed of the potential health and safety hazards, and trained in the appropriate handling and disposal procedures.

(e) Each facility shall monitor staff performance for adherence to the established handling and disposal procedures.

(f) Policy for disposal of these wastes by a health care facility shall be available for review by the Department of Health Services or the Commissioner of Consumer Protection.

Sec. 21a-66-3. Purchase, possession, control and use of hypodermic needles and syringes

(a) The purchase, possession, control, and use of hypodermic needles and syringes by commercial or industrial firms pursuant to Section 21a-65(a)(6) of the Connecticut General Statutes shall be considered to be authorized by the Commissioner of Consumer Protection provided that such businesses attest to the following in a written statement which they shall provide to the commissioner:

(1) that there exists an essential need for such devices in any function of their operation;

(2) that there are no devices, tools, or equipment modifications which may be used as an alternative to the use of hypodermic needles and syringes;

(3) that there shall be maintained only those quantities of hypodermic needles and syringes which are essential for normal efficient operations;

(4) that security safeguards and inventory control systems have been established which are adequate to detect any loss or diversion of hypodermic needles and syringes; and

(5) that access to stocks of hypodermic needles and syringes is limited to only those employees who have a legitimate need to handle these devices in the normal course of business.

(b) It shall be within the discretion of the Commissioner to determine whether such firms meet the requirements of subsection (a) of this section.

Regulations Concerning Drug Wholesalers

Sec. 21a-115-28. Definitions. For the purpose of Sections 21a-115-28 through Sections 21a-115-32 the following terms shall have the meanings indicated:

(1) "Commissioner" means the Commissioner of Consumer Protection;

(2)"Controlled substance" means a drug as defined in Chapter 420b, Section 21a-240(9) of the general statutes;

(3) "Drug" means an article defined in Chapter 418, section 21a-92(8) of the General statutes;

(4) "Drug sample" means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug;

(5) "Legend drug" shall have the definition stated in Chapter 382, Section 20--184a of the general statutes;

(6) "Over the counter drug" means a drug which is not a legend drug;

(7) "Registration" means a wholesaler certificate of registration issued in accordance with Chapter 417, Section 21a-70(b) of the general statutes; and

(8) "Wholesaler" means a person or firm defined in Chapter 417, Section 21a-70(a)(1) of the general statutes who distributes a drug, except that for the purposes of these regulations such distribution does not include intracompany sales or the distribution of drug samples by manufacturers.

Sec.21a-115-29. Minimum information required for registration as a wholesaler

The following information shall be required for each application for a registration or a renewal of a registration:

(1) the name, full business address, and telephone number of the registrant;

(2) All trade or business names used by the registrant;

(3) Addresses, telephone numbers, and the names of contact persons for all facilities used by the registrant for the storage, handling, and distribution of prescription drugs;

(4) The type of ownership or operation (i.e. partnership, corporation, or sole proprietorship);

(5) The name(s) of the owner and/or operator of the registrant, including:

(A) If a person, the name of the person;

(B) If a partnership, the name of each partner, and the name of the partnership;

(C) If a corporation, the name and title of each corporate officer and director, the corporate name, and the name of the State of incorporation; and

(D) If a sole proprietorship, the full name of the sole proprietor and the name of the business entity;

(6) An indication as to whether the registrant will distribute controlled substances, legend drugs and/or over the counter drugs as well as a statement concerning the types of drugs to be distributed; and

(7) A change in any information in this section shall be submitted to the Commissioner within 30 days of such change.

Sec.21a-115-30. Multiple locations

A wholesaler operating facilities at more than one location need only obtain a single registration provided that it does not store or distribute controlled substances and there is joint ownership and control of all the facilities operating under the single registration and all locations shall be subject to inspection in accordance with Chapter 418, Section 21a-118 of the general stat-

utes. If a wholesaler stores or distributes controlled substances, it shall register each facility separately.

Sec.21a-115-31. Personnel. Personnel employed by wholesalers shall have appropriate education and/or experience to assume responsibility for positions related to compliance with registration requirements.

Sec. 21a-115-32. Minimum requirements for the storage and handling of drugs and for the establishment and maintenance of drug distribution records by wholesaler

(a) Facilities. All facilities at which drugs are stored, warehoused, handles, offered, marketed, or displayed shall:

(1) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(2) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(3) Have a quarantine area for storage of drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;

(4) Be maintained in a clean and orderly condition; and

(5) Be free from infestation by insects, rodents, birds, or vermin of any kind.

(b) Security.

(1) All facilities operated by wholesalers shall be secure any unauthorized entry.

(2) Access from outside the premises shall be kept to a minimum and well controlled.

(3) The outside perimeter of the premises shall be well-lighted.

(4) Entry into areas where drugs are held shall be limited to authorized personnel.

(5) All facilities shall be equipped with an alarm system detect entry after business hours.

(6) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(7) In the case of wholesalers who are also licensed as pharmacies in accordance with Chapter 382, Section 20-168 of the general statutes, subdivisions (2) and (4) of this subsection shall apply only to areas where legend drugs are stored.

(c) Storage.

(1) All drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the current edition of an official compendium, such as the United States Pharmacopoeia/National Formulary(USP/NF).

(2)If no storage requirements are established for a drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that it's identity, strength, quality, and purity are not adversely affected.

(3) Appropriate measures shall be undertaken to ensure that drugs are stored under conditions of proper temperature and humidity and that such storage conditions are adequately documented.

(4) The record keeping requirements in subsection (f) of this section shall be followed for all stored drugs.

(d) Examination of materials.

(1) Upon receipt each outside shipping container shall be visibly examined for identity and to prevent the acceptance of contaminated drugs or drugs that are otherwise unfit for distribu-

tion. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(2) Each outgoing shipment shall be carefully inspected for identity of the drug products and to ensure that there is no delivery of drugs that have been damaged in storage or held under improper conditions.

(3) The record keeping requirements of subsection (f) of this section shall be followed for all incoming and outgoing drugs.

(e) Returned, damaged, and outdated drugs.

(1) Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other drugs until they are destroyed or returned to their supplier.

(2) Any drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other drugs until they are either destroyed or returned to the supplier.

(3) If the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be destroyed, or returned to the supplier, unless examination, testing, other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesaler shall consider, among other things, the condition under which the drug has been held, stored, or shipped before or during its return and the conditions of the drug and its container, carton, or labeling, as a result of storage or shipping.

(4) The record keeping requirements in subsection (f) of this section shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated drugs.

(f) Recordkeeping.

(1) Wholesalers shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of drugs. These records shall include the source of the drugs, including the name and principal address of the seller or transferor, the address of the location from which the drugs were shipped or in the case of distribution the name and address of the purchaser; the identity and quantity of the drugs received and distributed or disposed of; and the dates of receipt and distribution or other disposition of the drugs. In the case of registered wholesalers who are also licensed as pharmacies in accordance with Chapter 382, Section 20-168 of the general statutes, no records shall be required to be maintained for the receipt or disposition of over-the-counter drugs.

(2) Inventories and records shall be made available for inspection and photocopying by authorized Federal, State or local officials for a period of 3 years following disposition of the drugs.

(3) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within 2 working days of a request by an authorized official of a Federal, State or local agency.

(g) Written Policies and Procedures. Wholesalers shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesalers shall include in their written policies and procedures the following:

(1) A procedure whereby the oldest approved stock of a drug product is distributed first. The procedure may permit deviation from this requirement, if such deviation is temporary and appropriate;

(2) A procedure to be followed for handling recalls and withdrawals of drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to: any action initiated at the request of the U.S. Food and Drug Administration or other Federal, State, or local law enforcement or government agency; any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design;

(3) A procedure to ensure that the wholesaler prepare for, protect against, and handle any crises that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency;

(4) A procedure to ensure that any outdated drugs be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated drugs. This documentation shall be maintained for 3 years after disposition of the outdated drugs; and

(5) In the case of wholesalers who are also licensed as pharmacies in accordance with Chapter 382, Section 20-168 of the general statutes, the requirements of this subsection shall apply to legend drugs only.

(h) Responsible persons.

Wholesalers shall establish and maintain lists of officers, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

Regulations Concerning the Designation of Controlled Drugs

Sec. 21a-243-1. Volatile substances

(a) The following volatile substances are hereby designated as controlled drugs to the extent that said chemical substances or compounds containing said chemical substances are sold, prescribed, dispensed, compounded, possessed or controlled or delivered or administered to another person, with the purpose that said chemical substances shall be breathed, inhaled, sniffed or drunk to induce a stimulant, depressant or hallucinogenic effect upon the higher functions of the central nervous system: Acetone; toluol; trichloroethylene; isopropanol; methanol; ether; methyl cellosolve acetate; toluene; hexane; butyl alcohol; benzene; methyl ethyl ketone; cyclohexanone; pentochlorophenol; ethyl acetate; methyl isobutyl ketone; trichloroethane, and dichlorodifluoromethane.

(b) Insofar as it is the express intent of these regulations to provide medical treatment whenever possible, there is hereby created the presumption that one who is found to have inhaled or to be under the influence of the above-described volatile substances shall be deemed to be psychologically dependent upon said volatile substances.

(c) To the extent that it is possible, medical treatment rather than criminal sanctions shall be afforded individuals who breathe, inhale, sniff or drink the above-named volatile substances.

Sec. 21a-243-2. Criminal liability of vendor

No vendor of the aforementioned volatile substances shall be deemed to have violated the provisions of chapter 420b of the general statutes insofar as sale, dispensing or delivering of one or

more of said volatile substances or compounds containing said chemical substances is concerned, unless he knew or should have known of the improper purpose to which said substance was to be put.

Sec. 21a-243-3. When volatile substances not controlled drug.
The above drugs are designated as controlled drugs only for the limited purpose stated in section 21a-243-1. Insofar as substances containing said drugs are possessed, sold, dispensed, compounded or delivered for licit purposes, i.e., other than to produce a stimulant, depressant or hallucinogenic effect upon the higher functions of the central nervous system by breathing, inhaling, sniffing or drinking, such substances are expressly not controlled and neither the regulatory provisions, including but not limited to record keeping, licensing, and the writing of prescriptions nor the criminal sanctions and proscriptions of chapter 420b of the general statutes shall apply.

Sec. 21a-243-4. Anesthesia
The breathing, inhalation, sniffing or drinking of anesthesia for medical or dental purposes under the direction of a physician, dentist or osteopath acting in the course of his professional practice, is determined to be a licit purpose and not in contravention of these regulations or the provisions of chapter 420b of the general statutes.

Sec. 21a-243-5. Controlled drugs
The following substances are hereby designated as controlled drugs for all purposes of chapter 420b of the general statutes: Datura stramonium, hyoscyamus niger, atropa belladonna or the alkaloids atropine, hyoscyamine, belladonnine, apoatropine, or any mixture of these alkaloids such as daturine, or the synthetic homatropine or any salts of these alkaloids. Any drug or preparation containing any of the above-mentioned substances which is permitted by federal food and drug laws to be sold or dispensed without a prescription or written order shall not be a controlled drug.

Sec. 21a-243-6. Amyl nitrate
Amyl nitrate is hereby designated as a controlled drug as defined under chapter 420b of the general statutes.

Schedules of Controlled Substances

21a-243-7. Controlled substances in schedule I
The controlled substances listed in this regulation are included by whatever official, common, usual, chemical, or trade name designation in Schedule I:

(a) Any of the following opiates, including their isomers, esters, ethers, salts and salts of isomers, esters and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation:

(1) Acetylalpha-methylfentanyl;
(2) Acetylmethadol;
(3) Allylprodine;
(4) Alphacetylmethadol (except Levo-alphacetylmethadol or LAAM);
(5) Alphameprodine;
(6) Alphamethadol;

(7) Alpha-methylfentanyl;
(8) Alphamethylthiofentanyl;
(9) Benzethidine;
(10) Benzylfentanyl;
(11) Betacetylmethadol;
(12) Beta-hydroxy-fentanyl;
(13) Beta-hydroxy-3-methylfentanyl;
(14) Betameprodine;
(15) Betamethadol;
(16) Betaprodine;
(17) Clonitazene;
(18) Dextromoramide;
(19) Diampromide;
(20) Diethylthiambutene;
(21) Difenoxin;
(22) Dimenoxadol;
(23) Dimepheptanol;
(24) Dimethylthiambutene;
(25) Dioxaphetyl Butyrate;
(26) Dipipanone;
(27) Ethylmethylthiambutene;
(28) Etonitazene;
(29) Etoxeridine;
(30) Furethidine;
(31) Hydroxypethidine;
(32) Ketobemidone;
(33) Levomoramide;
(34) Levophenacylmorphan;
(35) 3-methylfentanyl;
(36) 3-methylthiofentanyl;
(37) Morpheridine;
(38) Noracymethadol;
(39) Norlevorphanol;
(40) Normethadone;
(41) Norpipanone;
(42) Para-fluorofentanyl;
(43) Phenadoxone;
(44) Phenampromide;
(45) Phenomorphan;
(46) Phenoperidine;
(47) Piritramide;
(48) Proheptazine;
(49) Properidine;
(50) Propiram;
(51) Racemoramide;
(52) Thenylfentanyl;
(53) Thiofentanyl;
(54) Tilidine;
(55) Trimeperidine.

(b) Any of the following opium derivatives, their salts, isomers and salts of isomers, unless specifically excepted whenever the existence of these salts, isomers and salts of isomers is possible within the specific chemical designation:

(1) Acetorphine;
(2) Acetyldihydrocodeine;
(3) Benzylmorphine;
(4) Codeine methylbromide;
(5) Codeine-N-oxide;
(6) Cyprenorphine;
(7) Desomorphine;
(8) Dihydromorphine;
(9) Drotebanol;
(10) Etorphine, except hydrochloride salts;
(11) Heroin;
(12) Hydromorphinol;
(13) Methyldesorphine;
(14) Methyldihydromorphine;
(15) Morphine methylbromide;
(16) Morphine methylsulfonate;
(17) Morphine-N-oxide;
(18) Myrophine;
(19) Nicocodeine;
(20) Nicomorphine;
(21) Normorphine;
(22) Pholcodine;
(23) Thebacon.

(c) Any material, compound, mixture or preparation which contains their salts, isomers and salts of isomers, unless specifically excepted, whenever the existence of these salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) 4-bromo-2,5-dimethoxyamphetamine; or 4-bromo-2,5-DMA;
(2) 2,5-dimethoxyamphetamine; or 2,5-DMA;
(3) 2,5-Dimethoxy-4-ethylamphetamone or DOET;
(4) 3,4-Methylenedioxy-N-ethylamphetamine;
(5) 1-methyl-4-phenyl-4-propionoxypiperidine; or MPPP;
(6) 3,4-methylenedioxymethamphetamine; or MDMA;
(7) 4-methoxyamphetamine; or PMA;
(8) 5-methoxy-3,4-methylenedioxy-amphetamine;
(9) 5-Methoxy-NN-Diisopropyltryptamine(5-METHOXY-DIPT);
(10) 4-methyl-2,5-dimethoxyamphetamine; or DOM; or STP
(11) 3,4-methylenedioxy amphetamine; or MDA;
(12) 3,4,5-trimethoxy amphetamine;
(13) Benzylpiperazine or BZP;
(14) Bufotenine or Mappine;
(15) Alphaethyltryptamine;
(16) Diethyltryptamine or DET;
(17) Dimethyltryptamine or DMT;
(18) Ibogaine;
(19) Lysergic acid diethylamide;
(20) Marihuana;
(21) Mescaline;

(22) Parahexyl or Synhexyl;
(23) Peyote, meaning all parts of the plants;
(24) 1-(2-phenylethyl)-4-phenyl-4-acetoxypiperidine; or PEPAP;
(25) N-ethyl-3-piperidyl benzilate;
(26) N-methyl-3-piperidyl benzilate;
(27) Psilocybin;
(28) Psilocyn;
(29) Tetrahydrocannabinols except Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a united states food and drug administration approved product;
(30) Ethylamine analog of phencyclidine, Cyclohexamine or PCE;
(31) 4-Bromo-2,5-dimethoxyphenethylamine;
(32) Pyrrolidine analog of phencyclidine, PCP or PHP;
(33) [1-pyrrolidine] 1-[1-(2-THIENYL)CYCLOHEXYL]PYRROLIDINE;
(34) Thiophene analog of phencyclidine, TPCP or TCP.
(35) Tiletamine or 2-(ethylamino)-2-(2-thienyl)-cyclohexanone;
(36) Trifluoromethylphenylpiperazinem or TFMPP.

(d) Any material, compound, mixture or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, their salts, isomers and salts of isomers unless specifically excepted, wherever the existence of these salts, isomers and salts of isomers is possible within the specific chemical designation:

(1) Gamma-hydroxy butyric acid, except if contained in a drug product for which an application has been approved under section 505 of the federal food, drug and cosmetic act;
(2) Gamma-butyrolactone;
(3) Mecloqualone;
(4) Methaqualone; or
(5) Zolazepam.

(e) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers:

(1) Aminorex;
(2) 4-methylaminorex;
(3) Cathinone;
(4) Fenethylline;
(5) Methcathinone;
(6) N-ethylamphetamine;
(7) N,N-dimethylamphetamine.

Sec. 21a-243-8. Controlled substances in schedule II

The controlled substances listed in this regulation are included by whatever official, common, usual, chemical, or trade name designation in Schedule II:

(a) Any of the following substances, except those narcotic drugs listed in other schedules, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by combination of extraction and chemical synthesis:

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate excluding Apomorphine, Dextrorphan, Nalbuphine, Naloxone, Naltrexone, and their salts, but including the following: Raw opium, opium extracts, opium fluid extracts, powdered opium,

granulated opium, tincture of opium, codeine, ethylmorphine, etorphine hydrochloride, hydrocodone, hydromorhone, metopon, morphine, oxycodone, oxymorphone and thebaine;

(2) any salt, compound,isomer, derivative or preparation thereof which is chemically equivalent or identical with any of the substances referred to in paragraph (1), but not including the isoquinoline alkaloids of opium;

(3) opium poppy and poppy straw;

(4) coca leaves and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, but not including decocainized coca leaves or extractions which do not contain cocaine or ecgonine;

(5) concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid or powder form which contains the phenanthrine alkaloids of opium poppy).

(b) Any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation, Dextrorphan and Levopropoxyphene excepted:

(1) Alfentanil;

(2) Alphaprodine;

(3) Anileridine;

(4) Bezitramide;

(5) bulk Dextropropoxyphene (nondosage forms);

(6) Carfentanil;

(7) Dihydrocodeine;

(8) Diphenoxylate;

(9) Fentanyl;

(10) Isomethadone;

(11) Levo-alphacetylmethadol or LAAM;

(12) Levomethorphan;

(13) Levorphanol;

(14) Metazocine;

(15) Methadone;

(16) Methadone-intermediate,4-cyano-2-dimethylamino-4,4- diphenylbutane;

(17) Moramide-Intermediate,2-methyl-3-morpholino-1,1-diphenyl-propane-carboxylic acid;

(18) Pethidine (Meperidine);

(19) Pethidine-Intermediate-A,4-cyano-1-methyl-4-phenylpiperidine;

(20) Pethidine-Intermediate-B,ethyl-4-phenylpiperidine-4- carboxylate;

(21) Pethidine-Intermediate-C, 1-methyl 4-phenylpiperidine-4-carboxylic acid;

(22) Phenazocine;

(23) Piminodine;

(24) Racemethorphan;

(25) Racemorphan;

(26) Remifentanil;

(27) Sufentanil.

(c) Unless excepted or placed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a potential for abuse associated with a stimulant effect on the central nervous system:

(1) Amphetamine, its salts, optical isomers, and salts of its optical isomers;

(2) any substance which contains any quantity of meth-amphetamine, including its salts, isomers, and salts of isomers;

(3) Methylphenidate;

(4) Phenmetrazine and its salts.

(d) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Amobarbital;

(2) Glutethimide;

(3) Pentobarbital;

(4) Phencyclidine; and

(5) Secobarbital.

(e) Hallucinogenic Substances:

(1) Nabilone.

(f) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances:

(1) Immediate precursor to Amphetamine and Methamphetamine; Phenylacetone (some trade names or other names); phenyl-2-propanone; P2P; benzyl methyl ketone; methyl benzyl ketone;

(2) immediate precursors to phencyclidine (PCP);

(i) 1-phencylohexylamine;

(ii) 1-piperidinocyclohaxanecarbonitrile (PCC).

Sec. 21a-243-9. Controlled substances in schedule III

The controlled substances listed in this regulation are included by whatever official, common, usual, chemical, or trade name designation in Schedule III:

(a) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Benzphetamine;

(2) Chlorphentermine

(3) Clortermine;

(4) Phendimetrazine.

(b) Unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a potential for abuse associated with a depressant effect on the central nervous system:

(1) Any compound, mixture or preparation containing: Amobarbital, Secobarbital, Pentobarbital or any salt thereof and one or more other active medicinal ingredients which are not listed in any schedule;

(2) Any suppository dosage form containing Amobarbital, Secobarbital, Pentobarbital or any salt of any of these drugs and approved by the Food and Drug Administration for marketing only as a suppository;

(3) Any substance which contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid, except those substances which are specifically listed in other schedules, except that the following analgesic products
shall not be considered to be controlled substances:

(A) Products containing a ratio of fifteen milligrams of long or intermediate acting barbiturates combined with at least one of the following:

(i) 188 mg aspirin;

(ii) 375 mg salicylamide; or

(iii) 70 mg phenacetin, acetanilid or acetaminophen;

(B) Products containing a ratio of fifteen milligrams of short acting barbiturates combined with at least one of the following:

(i) 307 mg aspirin;

(ii) 614 mg salicylamide; or

(iii) 106 mg phenacetin, acetanilid or acetaminophen;

(4) Any compound, mixture or preparation containing equal weights of both tiletamine and zolazepam or any salt thereof and not mixed with other psychoactive substances;

(5) Chlorhexadol;

(6) Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a United States Food and Drug Administration approved drug product;

(7) Ketamine or any salt thereof;

(8) Lysergic acid;

(9) Lysergic acid amide;

(10) Methyprylon;

(11) Sulfondiethylmethane;

(12) Sulfonethylmethane;

(13) Sulfonmethane.

(c) Buprenorphine.

(d) Nalorphine.

(e) Any material, compound, mixture or preparation containing limited quantities of any of the following narcotic drugs or any salts thereof:

(1) Not more than 1.8 grams of codeine, or any of its salts, per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium;

(2) not more than 1.8 grams of codeine, or any of its salts, per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(3) not more than 300 milligrams of dihydrocodeinone, or any of its salts, per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium;

(4) not more than 300 milligrams of dihydrocodeinone, or any of its salts, per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(5) not more than 1.8 grams of dihydrocodeine, or any of its salts, per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(6) not more than 300 milligrams of ethylmorphine, or any of its salts, per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more ingredients in recognized therapeutic amounts;

(7) not more than 500 milligrams of opium per 100 milliliters or per 100 grams, or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(8) not more than 50 milligrams of morphine, or any of its salts, per 100 milliliters or per 100 grams with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(f) Unless expressly intended for administration through implants to nonhuman species and approved for such use by the Federal Food and Drug Administration, any anabolic steroid including but not limited to, any of the following, or any isomer, ester, salt or derivative of the following that acts in the same manner on the human body:

(1) Boldenone;
(2) Chlorotestosterone;
(3) Clostebol;
(4) Dehydrochlormethyltestosterone;
(5) Dihydrotesterone;
(6) Drostanolone;
(7) Ethylestrenol;
(8) Fluoxymesterone;
(9) Formebulone;
(10)Mesterolone;
(11)Methandienone;
(12)Methandranone;
(13)Methandriol;
(14)Methandrostenolone;
(15)Methenolone;
(16)Methyltesterone;
(17)Mibolerone;
(18)Nandrolone;
(19)Norethandrolone;
(20)Oxandrolone;
(21)Oxymesterone;
(22)Oxymetholone;
(23)Stanolone;
(24)Stanozolol;
(25)Testolactone;
(26)Testosterone;
(27)Trenbolone.

(g) Chorionic gonadotropin.

(h) Any quantity of the following substances having a depressant effect on the central nervous system, including their salts, isomers and salts of such isomers, and esters:

(1) Gamma-hydroxy butyric acid if contained in a product for which an application has been approved under section 505 of the federal food, drug and cosmetic act; or

(2) Gamma-butyrolactone.

Sec. 21a-243-10. Controlled substances in schedule IV

The controlled substances listed in this regulation are included by whatever official, common, usual, chemical, or trade name designation in Schedule IV:

(a) Any material, compound, mixture or preparation which contains any quantity of the following substances having a potential for abuse associated with a depressant effect on the central nervous system:

(1) Alprazolam;
(2) Barbital;
(3) Bromazepam
(4) Camazepam;
(5) Chloral betaine;
(6) Chloral hydrate;
(7) Chlordiazepoxide;
(8) Clobazam;
(9) Clonazepam;
(10) Clorazepate;

(11) Clotiazepam;
(12) Cloxazolam;
(13) Delorazepam;
(14) Diazepam;
(15) Dochloralphenazone;
(16) Estazolam;
(17) Etholorvynol;
(18) Ethinamate;
(19) Ethyl-lofiazepate;
(20) Fludiazepam;
(21) Flunitrazepam;
(22) Flurazepam;
(23) Halazepam;
(24) Haloxazolam;
(25) Ketazolam;
(26) Loprazolam;
(27) Lorazepam;
(28) Lormetazepam;
(29) Mebutamate;
(30) Medazepam;
(31) Meprobamate;
(32) Methohexital;
(33) Methylphenobarbital (mephobarbital);
(34) Midazolam;
(35) Nimetazepam;
(36) Nitrazepam;
(37) Nordiazepam;
(38) Oxazepam;
(39) Oxazolam;
(40) Paraldehyde;
(41) Petrichloral;
(42) Phenobarbital;
(43) Pinazepam;
(44) Prazepam;
(45) Quazepam;
(46) Temazepam;
(47) Tetrazepam;
(48) Triazolam;
(49) Zaleplon;
(50) Zolpidem;

(b) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Cathine;
(2) Diethylpropion;
(3) Fencamfamin;
(4) Fenproporex;
(5) Mazindol;

(6) Mefenorex;
(7) Modafinil;
(8) Pemoline
(9) Phentermine
(10) Pipradol;
(11) Sibutramine
(12) SPA [(-)dimethylamino-1,2-diphenylethane].

(c) Any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers, and salts of isomers is possible:

(1) Fenfluramine.

(d) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, or any salts thereof:

(1) Not more than 1 milligram of Difenoxin and not less than 25 micrograms of Atropine Sulfate per dosage unit;

(2) Dextropropoxyphene [alpha-(+)-4-dimethylamino-1, 2-diphenyl-3methyl-2-propionoxybutane].

(e) Unless specifically exempted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances, including its salts:

(1) Butorphanol; or

(2) Pentazocine.

Sec. 21a-243-11. Controlled substances in schedule V

The controlled substances listed in this regulation are included by whatever official, common, usual, chemical, or trade name designation in Schedule V:

(a) Any compound, mixture, or preparation containing limited quantities of any of the following controlled drugs, which also contain one or more noncontrolled active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation, valuable medicinal qualities other than those possessed by the controlled drug alone:

(1) not more than 200 milligrams of codeine, or any of its salts, per 100 milliliters or per 100 grams;

(2) not more than 100 milligrams of dihydrocodeine, or any of its salts, per 100 milliliters or per 100 grams;

(3) not more than 100 milligrams of ethylmorphine, or any of its salts, per 100 milliliters or per 100 grams;

(4) not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit;

(5) not more than 100 milligrams of opium per 100 milliliters or per 100 grams;

(6) not more than 0.5 milligrams of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

(b) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of such isomers:

(1) Pyrovalerone

Regulations Concerning Minimum Security and Safeguards for Storage and Handling of Controlled Substances

Sec. 21a-262-1. Definitions

(a) Controlled Substances means a drug, substance, or immediate precursor so designated as a controlled drug or controlled substance pursuant to state and/or federal drug laws and regulations.

(b) Schedules of Controlled Substances. For security purposes, each particular controlled substance shall be considered to be in the schedule as designated in each particular instance by applicable state and/or federal drug laws or regulations. In instances of conflict between state and federal drug laws or regulations, the controlled substances shall be considered to be in the schedule providing the highest degree of control.

(c) Registrant means any person of firm registered with the federal, government for conduct of any business activity with controlled substances. The person signing the federal application for registration for controlled substances shall be considered to be the registrant for security purposes.

(d) Classification of Registrants. For security purposes, registrants shall be classified according to the business activity for which they are registered under the federal controlled substances act.

(e) Controlled Substance(s) Units: A controlled substance unit shall be a unit consisting of a quantity of controlled
substance(s) which shall be determined according to the following formula:
#100 Tablets or Capsules--shall be 1 unit
One pint of a liquid--shall be 1 unit
1/8 ounce of a powder, crystal, flake, or granule shall be 1 unit
One multiple dose vial--shall be 1 unit
Ten suppositories--shall be 1 unit
Ten single dose Ampules, Tubexes, Dosettes, Hyporettes, or other single dose package forms for injection whether powder or in solution shall be 1 unit

The quantity of controlled substance(s) stocked by any registrant shall be determined for security purposes by totaling the number of controlled substance(s) units currently on hand. Partial containers of controlled substances shall be considered as being full when determining the total quantity of controlled substance stock. Larger package sizes shall be counted according to the number of controlled substance units they contain. Package sizes less than a full controlled substance unit shall be counted as the fraction of a controlled substance unit which the package size contains, i.e., #50 Tablets shall be counted as .5 controlled substance units.

(f) An approved safe or safe(s) as used in Secs.
21a-262-1--21a-262-10 inclusive means any safe(s) which has been approved prior to January 1, 1975 or any safe(s) which conforms to or exceeds all of the following standards.
(1) Safe Manufacturers National Association certified as being Class A, B or C
(2) Underwriters Laboratories, Inc. certified as being inspected for one or two hours.
(3) Underwriters Laboratories. Inc. certification as being equipped with a relocking device.
(4) Weight of 750 pounds or more or rendered immobile by being securely anchored to a permanent structure of the building.
(5) Adequate interior space to store all controlled substances required to be kept within.

(g) An approved vault as used in Secs. 21a-262-1--21a-262-4 inclusive, means a vault approved prior to January 1, 1975 or a vault constructed after January 1, 1975 and meeting the following specifications or equivalent:

(1) Walls, floors, and ceilings constructed of at least 8 inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with 1/2 inch steel rods tied 6 inches on center, or the structural equivalent to such reinforced walls, floors, and ceilings.

(2) The door of the vault must contain a multiple-position combination lock or the equivalent, a relocking device or equivalent and steel plate with a thickness of at least 1/2 inch. (The GSA Class 5 rated steel door meets all the qualifications for the vault door.)

(3) The vault, if operations require it to remain open for frequent access, must be equipped with a "day gate" which is self-closing and self-locking or the equivalent. If the operation requires only that the vault be opened infrequently, such as to remove raw material in the morning and return raw material at night, and is always relocked immediately after use, a "day gate" is not required.

(4) The walls, floor, and ceiling of the vault must be equipped with an alarm which, when unauthorized entry is attempted, transmits a signal directly to a central station protection company, or a local or state police agency which has a legal responsibility to respond, or a 24-hour control station operated by the registrant. If necessary, due to local conditions or other problems, holdup buttons shall be placed at strategic points of entry to the perimeter area of the vault.

(5) The vault door must be equipped with a contact switch.

(6) The vault must have at least one of the following:

a. Complete electrical lacing of the walls, floor and ceiling or

b. Sensitive ultrasonic equipment within the vault or

c. A sensitive sound accumulator system or

d. Such other device designed to detect illegal entry as may be approved by the Commissioner of Consumer Protection.

(7) The electrical alarm system must be certified as being an Underwriters Laboratories, Inc., approved system and installation.

Sec. 21a-262-2. Security requirements

(a) Requirements for minimum security and safeguard standards for storage and handling of controlled substances may be determined for each registrant by the Commissioner of Consumer Protection after consideration of the protection offered from an overall standpoint in instances wherein other security measures provided exceed those specifically stated. If the registrant has provided other safeguards which can be regarded into as an adequate substitute for some element of protection required of such registrant such as supervised watchman service, full electrical protection of the building, electric alarms, etc., such added protection may be taken into account in evaluating overall required security measures. In cases where special hazards exist such as extremely large stock, exposed handling, unusual vulnerability to loss, theft, diversion, or robbery, additional safeguards will be required by the Commissioner of Consumer Protection which may include approved vault(s), approved safe(s), electrical alarm protection, and/or hold up button(s).

(b) In all instances, registrants shall maintain all stocks of controlled substances in all schedules in a secure area or location accessible only to specifically authorized personnel. Such specific authorization should be given by registrants only to the minimum number of employees absolutely essential for efficient operation. All controlled substances should be stored in such a manner as to prevent theft or diversion of these preparations.

(c) In all instances, registrants shall maintain all equipment used for storage of controlled substances such as approved vault(s), approved safe(s), caged areas, cabinets, enclosures, etc., securely locked except for the actual time required to remove or replace needed items. Locks shall be kept in good working order with keys removed therefrom. Keys to the locks shall not be left in a location accessible to other than specifically authorized personnel.

(d) Any controlled substance(s) stored at any location not stored in compliance with Secs. 21a-262-1--21a-262-10 inclusive, or at a location other than that for which the person, firm, or business activity is registered under the Federal Controlled Substances Act shall be subject to seizure by the Commissioner of Consumer Protection. This action of seizure shall be considered as being in the best interests of the general public and said Commissioner shall not be held liable for any loss of revenues suffered by the person surrendering the drugs.

(e) Any wholesaler, manufacturer, or laboratory licensed by the Commissioner of Consumer Protection, who after due process, has his license revoked or suspended by said Commissioner, or who does not within 30 days apply for relicensure shall upon loss of said license dispose of his entire stock of controlled substances under conditions approved by the Commissioner or surrender his entire supply of controlled substances to said Commissioner. Any Licensed Pharmacy or any Practitioner who has his license revoked or suspended by his respective Licensing Board or who does not apply for relicensure, shall dispose of his entire stock of Controlled Substances under conditions approved by the Commissioner of Consumer Protection or shall surrender his entire stock of Controlled Substances to said Commissioner. This action of surrender shall be considered as being in the best interest of the general public, and said Commissioner shall not be held liable in any way for any loss of revenue suffered by the person surrendering these drugs.

(f) If any case where a loss, theft, burglary, or diversion of controlled substances has occurred, the Commissioner of Consumer Protection may require additional security safeguards which may include storage of any controlled substance(s) in an approved vault, approved safe, separate locked caged area, locked room or enclosure, or a substantially constructed locked steel or wood cabinet or under effective electrical protection within 90 days of any such occurrence. In the case of hospitals, 180 days shall be allowed for this purpose.

(g) Registrants shall not maintain any stock of controlled substance(s) in excess of the quantity actually required for normal, efficient operation.

Sec. 21a-262-3. Disposition of drugs

(a) Disposal of undesired, excess, unauthorized, obsolete, or deteriorated controlled substances shall be made by a registrant, person having title to, enforcement or court official, executor of an estate, or any other person in the following manner:

(1) By transfer to a person or firm registered under the Federal Controlled Substances Act and authorized to possess such controlled substances providing all state and federal required procedures are complied with.

(2) By following procedures as outlined in Sections 1307.21 of the Code of Federal Regulations.

(3) By the following manner in the case of hospital pharmacies where small quantities of less than No. 10 controlled substance units are involved on any separate occasion:

(a) By destruction in such a manner as to render the controlled substance(s) nonrecoverable.

(b) By destruction conducted by a Connecticut licensed pharmacist in the presence of another Connecticut licensed pharmacist acting as a witness.

(c) By maintaining a separate record of each such destruction indicating the date, time, manner of destruction, the type, strength, form, and quantity of controlled substance(s) destroyed, and the signatures of the pharmacist destroying the controlled substance(s) and the pharmacist witness.

(4) By a manner rendering the controlled substance(s) nonrecoverable in cases where such controlled substance(s) are legally possessed by a person for his/her own personal use pursuant to a bonafide medical condition.

(5) By surrender without compensation of such controlled substance(s) to the Commissioner of Consumer Protection in all other instances.

(b) Reporting of loss, theft, or unauthorized destruction of controlled substances. Any loss, theft, or unauthorized destruction of any controlled substance(s) must be reported by a registrant within 72 hours of discovery of any such occurrence to the Commissioner of Consumer Protection as follows:

(1) Where through breakage of the container or other accident, otherwise than in transit, controlled substance(s) are lost or destroyed, the registrant shall make a signed statement as to the kinds and quantities of controlled substance(s) lost or destroyed and the circumstances involved. The statement shall be forwarded to the Commissioner of Consumer Protection and a copy retained by the registrant.

(2) Where controlled substance(s) are lost by theft or otherwise lost or destroyed in transit, the consignee, and the consignor if within this state, shall forward to the Commissioner of Consumer Protection a signed statement which details the facts, includes an accurate listing of the controlled substance(s) stolen, lost, or destroyed and specifies that the local authorities were notified. A copy of the statement shall be retained by the registrant.

Sec. 21a-262-4. Manufacturers, wholesalers, distributors, importers, and exporters

(a) Schedule II Stock if less than No. 250 controlled substance units shall be stored in an approved safe. If No. 250 or more controlled substance units all schedule II controlled substances shall be stored in an approved vault.

(b) Schedule III, IV, V Stock shall be stored in an approved vault, approved safe equipped with a separate effective electrical alarm system, or separate secure locked caged area, room, or enclosure equipped with a separate effective electrical alarm system. If a caged area or enclosure is used, such caged area or enclosure must be completely enclosed. If a caged area is used, construction must be of heavy gauge wire mesh having openings smaller than the smallest controlled substance(s) containers stocked.

(c) All controlled substances in the process of manufacture, distribution, transfer, or analysis shall be stored in such a manner as to prevent diversion; shall be accessible only to the minimum number of specifically authorized personnel essential for efficient operation; and shall be returned to the required security location immediately after completion of the procedure or at the end of the scheduled business day. If a manufacturing process cannot be completed at the end of a working day, the processing area or tanks, vessels, bins, or bulk containers containing controlled substances must be securely locked inside an area or building which affords adequate security.

Sec. 21a-262-5. Licensed pharmacies

(a) Schedule II Stock, if less than No. 150 controlled substance units a substantially constructed completely enclosed locked wood or metal cabinet shall be used for storage of all schedule II controlled substance stock. If No. 150 or more controlled substance units an approved safe shall be used for storage of all schedule II controlled substance stock. Pharmacies newly licensed and/or relocating after Jan. 1, 1975 shall be required to store all schedule II controlled substances in an approved safe.

(b) Schedule III, IV, V Stock shall be stored in an approved safe, substantially constructed locked metal or wood cabinet, or dispersed throughout stock within the pharmacy prescription compounding area providing requirements of Section 21a-262-2(b) are complied with and a loss, theft, or diversion of and controlled substance in and schedule has not occurred.

(c) In every case where loss, theft, burglary, or diversion other than armed robbery during regular scheduled business hours of any controlled substance in any schedule has occurred from a licensed pharmacy, an approved safe shall be required within 90 days of such occurrence for the storage of all schedule II and III controlled substance stock, and additional safeguards shall be required for schedule IV and V controlled substance stock.

(d) The Commissioner of Consumer Protection may require any licensed pharmacy to store any controlled substance stock in an approved safe, or locked substantially constructed cabinet for security purposes when overall conditions warrant additional safeguards.

Sec. 21a-262-6. Practitioners including but not limited to medical doctors, dentists, veterinarians, osteopaths, and podiatrists

(a) Schedule II and III Controlled Substance Stock, if total is No. 15 controlled substance units or less shall be stored in a locked substantially constructed steel or wood cabinet in a securely safeguarded location. If the total quantity of schedule II and III controlled substance stock is more than 15 controlled substance units, such stock shall be stored in an approved safe. In the case of veterinary practitioners an additional No. 25 controlled substance units of schedule II or III controlled substance stock of the barbiturate type, for use solely for animal anesthesia or animal euthenasia, may be stored in a locked substantially constructed steel or wood cabinet.

(b) Schedule IV and V Controlled Substance Stock shall be stored in a locked substantially constructed steel or wood cabinet or in a securely safeguarded location.

(c) In no case shall a practitioner's controlled substance stock be left unsecured or unattended in an examining room, treatment room, automobile, or in any other location accessible to nonauthorized persons.

Sec. 21a-262-7. Laboratories other than hospital clinical laboratories

(a) Schedule I and II Controlled Substance Stock shall be stored in an approved safe except where schedule II stock of the barbiturate type is used solely for its sedative or anesthetic effect on animals and not more than No 10 Controlled Substance units are stocked, in which cases security as outlined for schedule III controlled substances in Section 21a-262-7(b) will apply. In instances in laboratories where schedule I or II stock may be unstable, of extremely small quantity, or of such a nature as to require special storage conditions, the Commissioner of Consumer Protection may approve of other security safeguards on an individual basis in lieu of those required by Secs. 21a-262-1-21a-262-10 inclusive

(b) Schedule III, IV or V Controlled Substances Stock shall be stored separately from other drugs and substances in an approved safe or separate secure locked location accessible only to the minimum number of specifically authorized personnel essential for efficient operation.

(c) Controlled Substances in the process of testing, use, or research shall be immediately returned to the required storage location upon completion of each such process.

Sec. 21a-262-8. Pharmacies or other areas wherein controlled substances are stored, prepared, or dispensed exclusive of those specifically referred to in section 21a-262-9 and section 21a-262-10 located within licensed hospitals, mental health hospitals, mental retardation facilities, training schools, correctional institutions, juvenile training or youth services facilities, educational institutions, health maintenance organizations, health facilities, and within other care giving institutions or establishments including those which are private, state, or municipally operated, and including hospital drug rooms, hospital satellite pharmacies, and hospital clinical laboratories.

(a) Schedule II and III Controlled Substance Stock in quantities of less than No. 150 controlled substance units shall be stored separately from other drugs and substances in a separate secure substantially constructed locked metal or wood cabinet. In the case of Hospital Clinical Laboratories, Schedule II Controlled Substance stock shall be stored in an approved safe. Schedule II and III controlled substance stock in quantities of No. 150 controlled substance units or more but less than No. 1000 controlled substance units shall be stored in an approved safe. Schedule II and III controlled substance stock in quantities of No. 1000 controlled substance units or more shall be stored in a completely enclosed masonry room or equivalent equipped with a vault-type

steel door with horizontal or vertical locking bolts, having a three-tumbler combination lock and a relocking device. The completely enclosed masonry room or equivalent, if operations require it to be opened for frequent access, must be equipped with a "day gate" which is self-closing and self-locking or the vault type steel door must be equipped with a key locking device or an equivalent day locking device.

Completely enclosed masonry rooms or equivalents constructed after January 1, 1975, must be equipped with an electrical alarm system which, when unauthorized entry is attempted, transmits a signal directly to a central station protection company, or a local or state police agency which has a legal responsibility to respond, or a 24-hour control station operated by the registrant.

(b) Schedule IV and V Controlled Substance stock shall be stored in a secure location within the pharmacy prescription compounding area or drug room. Schedule IV and V Controlled Substance Stock stored within hospital clinical laboratories shall be kept in a separate secure locked location.

(c) Controlled Substance Stock within any such pharmacy shall not be accessible to other than specifically authorized pharmacy personnel, and shall be handled by authorized pharmacy personnel only.

Sec. 21a-262-9. Hospital patient care areas, hospital nursing stations, other hospital drug storage locations, chronic and convalescent nursing homes, rest homes with nursing supervision, children's nursing homes, and areas and locations within correctional and/or juvenile training facilities, youth service facilities, mentally retarded facilities, and any other location other than pharmacies, hospital clinical laboratories, satellite pharmacies, or drug rooms, wherein drugs are stored, prepared, or dispensed not specifically referred to in Secs. 21a-262-1--21a-262-10 inclusive

(a) Schedule II Controlled Substances in small amounts not exceeding the quantity necessary for efficient operation kept at any specific individual area or location shall be stored in a locked substantially constructed nonportable and immobile metal cabinet or metal container within another separate locked enclosure. Keys shall not be the same for each of these locks and such keys shall be kept on two separated key rings or holders. Not more than one set of keys for the schedule II controlled substance cabinets shall be available to nonsupervisory personnel.

(b) At the beginning of each work period or shift, a nurse must be assigned responsibility for the security of schedule II controlled substance stock. Such responsibility shall be assumed by each said nurse who shall prepare a signed inventory indicating each kind and quantity of schedule II controlled substance received, the time and date received, and from whom received. This responsibility shall not be transferred or assigned to another nurse or person during the course of each work period or shift unless another signed inventory transferring responsibility is first prepared. For systems regulated under subsection (h) of this section, the requirements of this subsection shall be extended to include schedule III, IV and V controlled substance stock in addition to schedule II controlled substance stock.

(c) Schedule III, IV, V Controlled Substance Stock in small amounts not exceeding the quantity necessary for normal efficient operation of each individual unit shall be stored with Schedule II Controlled Substances in compliance with security measures as required per Section 21a-262-9(a) or separately from other drugs and/or substances in a separate secure locked nonportable immobile substantially constructed cabinet or container. Access to such cabinet or container shall be limited to a minimum number of personnel essential for efficient operation.

(d) Schedule III, IV, V Controlled Substance Stock in small quantities intended for emergency use only, may be stored within an emergency drug kit or on emergency crash carts equipped with disposable locking or sealing devices, provided adequate security measures for such controlled substance stock are maintained and required record-keeping procedures are complied with.

(e) The same security requirements shall apply for controlled substances obtained pursuant to individual patient(s) prescriptions as for stock controlled substances as outlined under this section 21a-262-9 inclusive. Controlled substances obtained pursuant to such individual patient(s) prescriptions shall not be used for any other patient(s) and when no longer required for the intended specific individual patient, shall be securely kept and safeguarded until properly disposed of.

(f) In cases involving Unit Dose or experimental, trial, new, or innovative drug distribution procedures, the Commissioner of Consumer Protection may approve of other controlled substance(s) security safeguards for a specific time period, in lieu of any required by Secs. 21a-262-1--21a-262-10 inclusive, on an individual basis after evaluating each such drug distribution procedure. Such approval may be extended indefinitely by said Commissioner upon such successful completion of the trial period. If approval is not given by said Commissioner prior to the implementation of any such drug distribution procedure, controlled substance security requirements as outlined in Secs. 21a-262-1--21a-262-10 inclusive shall apply.

(g) Where unwanted partial or individual doses of Controlled Substances are discarded by nursing personnel, a record of each such destruction must be made indicating the date and time of each such destruction; the name, form, strength, and quantity of Controlled Substance destroyed; the signature of the nurse destroying the Controlled Substance, and the signature of another nurse who witnesses such destruction. In other than hospital locations, an authorized person may witness such destruction.

(h) In cases involving distribution of an individual patient's controlled substance medication by means of the use of mobile medication carts within chronic and convalescent nursing homes, and rest homes with nursing supervision, the following security safeguards shall be approved in lieu of any required by section 21a-262-9(a) and (c); except that compliance with this subsection shall not be required of a facility using a mobile medication cart system previously approved for use in that facility by the commissioner of consumer protection. Compliance with this subsection by facilities with previously approved systems shall be in lieu of the requirements of such previously approved systems.

(1) Mobile medication carts shall be of substantial construction and shall incorporate the following security features:

(A) A separate, lockable, non-removable drawer or compartment for storage of all controlled substances,

(B) The key which locks the controlled substance drawer or compartment shall be different from the key(s) to all other locking devices on each cart and such keys shall not be interchangeable between carts within the same facility, and

(C) Locking mechanism(s) which will secure the entire contents of the cart without requiring the use of a key;

(2) Mobile medication carts when not in use shall be locked and stored within a limited access locked and enclosed medication room or closet or other substantially constructed enclosed structure;

(3) Mobile medication carts shall be securely locked at all times when unattended. All medication and injection equipment shall be stored within the locked cart. Locking devices shall be maintained in good working order;

(4) The separate controlled substance drawer or compartment shall be securely locked at all times except for the actual time required to remove or replace needed items or to conduct an audit;

(5) The keys to the controlled substance drawer or compartment of each mobile cart shall be separated from the keys to the other locking devices of that cart and shall be carried personally by the nurse responsible for the required controlled substance audit during each nursing shift and no duplicate keys shall be available to other than specifically designated supervisory personnel;

(6) Requirements of section 21a-262-9(b) concerning audits of controlled substance stocks shall be extended to include schedule III, IV, and V controlled substance stock in addition to schedule II controlled substance stock;

(7) Record keeping entries of controlled substances administered shall be made at the time of administration;

(8) The director of nursing or his/her nursing supervisor designee shall conduct unannounced documented audits of all controlled substance stocks on all units at least twice a month; and

(9) All controlled substance medications shall be inventoried when received and immediately placed into the controlled substance drawer or compartment within the mobile cart. Quantities of patients' controlled substance medications stored within mobile medication carts shall be limited to the minimum quantities necessary to provide for normal efficient operation and shall be promptly removed for proper disposition when no longer needed by the patient.

(i) In cases involving distribution of an individual patient's controlled substance medication by means of the use of mobile medication carts within chronic and convalescent nursing homes, and rest homes with nursing supervision, other security safeguards in lieu of any required by section 21a- 262-9(h) may be approved by the commissioner of consumer protection on an individual basis after evaluating the drug distribution procedure of the applicant for approval pursuant to this subsection.

Sec. 21a-262-10. Industrial health facilities, educational institution infirmaries, clinics, summer camps, and other institutions or establishments providing health care services including those which are group, private, state, and/or municipally operated

(a) Schedule II and III Controlled Substance Stock, if No. 15 controlled substance units or less shall be stored separate from other drugs and substances in a separate secure substantially constructed locked metal or wood cabinet. Schedule II and III Controlled Substance Stock if in excess of No. 15 controlled substance units shall be stored in an approved safe.

(b) Schedule IV and V Controlled Substance Stock shall be stored in a separate secure locked location or with Schedule II and III Controlled Substances in compliance with security measures as required per section 21a-262-10(a).

(c) Controlled Substances for Stock use shall be purchased or obtained by the medical director or physician in charge from a wholesaler or manufacturer of drugs, and shall be handled only by an authorized physician, Connecticut licensed pharmacist, or Connecticut licensed nurse. Controlled substances shall be the property of the medical director or physician in charge who shall be responsible for security requirements and record keeping procedures.

(d) The same security requirements shall apply for controlled substances obtained pursuant to patient(s) prescriptions as for stock controlled substances. Controlled substances obtained pursuant to such individual patient(s) prescriptions shall not be used for any other patient(s) and when no longer required for the intended specific individual patient shall be securely kept and safeguarded until properly disposed of. (Effective July 27, 1984)

Regulations Concerning the Registration of Practitioners for Controlled Substances

Sec. 21a-326-1. Definitions

(a) "Abuse or Excessive Use of Drugs" means the personal use of controlled substances by a practitioner or other registrant in such dosage and frequency not warranted by an existing medical condition or use of controlled substances solely for a stimulant, depressant, or

hallucinogenic effect which use is not within the medical consensus or stated in the medical literature as acceptable or proper.

(b) "Controlled Substance Schedules" means the grouping of drugs, schedules 1 through 5, as delineated in Section 21a-242 of Chapter 420b, Connecticut General Statutes or in regulations promulgated under the Code of Federal Regulation. Any particular controlled substance shall be deemed to be in the schedule wherein such controlled substance appears by its chemical or generic name within Sec. 21a-242 of Chapter 420b, Connecticut General Statutes or in regulations promulgated under the Code of Federal Regulation.

(c) "Course of Professional Practice" means the limitation of prescribing, dispensing, or administering of controlled substances for professional treatment authorized pursuant to regulations and/or statutes of the appropriate state licensing authority under which situations there must be a bona fide practitioner-patient relationship. The prescribing or dispensing of controlled substances for patients, friends, relatives, associates, and/or employees wherein a bona fide practitioner-patient relationship does not exist or wherein the practitioner has not medically evaluated the need for controlled substances shall not be considered to be in the "course of professional practice."

(d) "Effective Controls Against Diversion" means the implementation of the following controls on a regular basis necessary for the prevention of diversion of controlled substances:

(1) Prescribing, dispensing, or administering of controlled substances only after a proper medical evaluation.

(2) Maintaining of controlled substance record keeping and security requirements pursuant to Chapter 420b of the Connecticut General Statutes.

(3) Providing for adequate security of prescription blanks to prevent thefts and/or illegal use.

(4) Regular monitoring of patient(s) conditions in instances wherein continued or prolonged treatment with controlled substances is indicated.

(5) Refraining from knowingly prescribing controlled substances for persons abusing such controlled substances and/or using such controlled substances for purposes of maintenance of drug dependency unless pursuant to state and federal regulations pertaining to treatment of drug dependent persons.

(6) Compliance with all state and federal statutes and regulations concerning controlled substances.

(e)"Therapeutic or Other Proper Medical or Scientific Purposes" means the following:

(1) The prescribing, dispensing, or administering of a controlled substance for treatment of a specific disease or medical condition, recognized by medical consensus and/or stated in the literature of the manufacturers of the controlled substances as being the purposes for which the controlled substance is intended.

(2) Investigational use of a controlled substance by a researcher or scientist wherein documentation of necessity of use of such controlled substances is maintained.

(f) "Legend drug" is any article, substance, preparation or device which bears the legend: "CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT A PRESCRIPTION."

Sec. 21a-326-2. Registration applications and renewals Registration applications and renewals shall be on such forms as furnished by the Commissioner of Consumer Protection and shall whenever so indicated be signed by the applicant.

(a) All registration applications shall contain all information required by the Commissioner of Consumer Protection. Applications not inclusive of required data or those which are illegibly executed may be returned for correction.

(b) It shall be the responsibility of all practitioners, hospitals, or other institutions who propose to engage in distributing, prescribing, administering, dispensing, or using any controlled substance within this state to submit an application for registration with the appropriate fee to the

Commissioner of Consumer Protection. The Commissioner shall issue a certificate of registration in accordance with the provisions of Chapter 420c of the General Statutes.

(c) It shall be the responsibility of the applicant to submit his/her registration renewal application to the Commissioner at least one month prior to the expiration of his/her current registration.

(d) All practitioners, hospitals, clinics, or other authorized persons or facilities wishing to prescribe, administer, or dispense controlled substances shall obtain a certificate of registration issued by the commissioner of consumer protection as mandated by Section 21a-317 of the General Statutes. No controlled substance shall be prescribed, administered, or dispensed until such registration has been approved by the commissioner. Regulation fees shall not be prorated.

(e) For registration purposes applicants shall be classified as follows:

(1) Practitioner;

(2) Hospital;

(3) Clinic;

(4) Others.

All practitioners shall designate their specific professional practice; e.g., M.D., dentist, veterinarian, osteopath or podiatrist on their application for registration. Other applicants shall designate their appropriate title; i.e., Ph.D., Director, Director of Pharmacy, Administrator, President, Manager, etc.

Sec. 21a-326-3. Notification of failure to obtain or renew registration

The Commissioner of Consumer Protection shall notify the Federal Drug Enforcement Administration or its successor, of the failure of any practitioner or researcher to obtain or renew a valid state registration; or of any administrative action taken by the Commissioner resulting in the denial, surrender, suspension, or revocation of a registration or the limitation of the controlled substance schedules of a registration.

Sec. 21a-326-4. Responsibility of registrant

(a) It shall be the responsibility of a registrant who ceases to practice or who goes out of business to notify the Commissioner in writing five (5) days before such occurrence.

(b) It shall be the responsibility of the registrant to notify the Commissioner within thirty (30) days of any changes in information or data required on the registration application pursuant to which any registration is issued.

Sec. 21a-326-5. Registration of controlled substances

(a) It shall be the responsibility of the registrant to be registered in accordance with state and federal controlled substance laws for those particular controlled substance schedules incorporating those drugs used or to be used within the scope of his/her professional practice.

(b) A registrant may voluntarily surrender his/her controlled substance registration privileges in any or all controlled substance schedules to the Commissioner of Consumer Protection or may voluntarily refrain from registering in those controlled substance schedules not applicable to his/her professional practice or scientific research.

(c) The Commissioner of Consumer Protection may in accordance with Sections 21a-323 and 21a-324 of the General Statutes limit the schedules for which the practitioner is registered. (Effective: July 27, 1984